2013

The Presumption of Patentability

Sean B. Seymore

Article

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> [P]resumptions . . . are the mere artificial creatures of law, depending entirely on considerations of legal policy and convenience . . . .[1]

INTRODUCTION

The U.S. Patent and Trademark Office (Patent Office) has come under fire for issuing patents of questionable quality.[2] Patent quality can be defined as "the capacity of a granted patent to meet (or exceed) the statutory standards of patentability—most importantly, to [cover inventions which are] novel,

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† Professor of Law, Vanderbilt University Law School. J.D., University of Notre Dame, 2006; Ph.D. (Chemistry), University of Notre Dame, 2001; M.S.Chem., Georgia Institute of Technology, 1996; B.S., University of Tennessee, 1993. I thank Michael Abramowicz, Daniel Gervais, Timothy Holbrook, Lee Petherbridge, Sarah Rajec, John Whealan, and the participants in the George Washington University Law School Intellectual Property Speakers Series for their comments and criticisms on earlier drafts of this Article. I also thank Vanderbilt University Law School and the Arnold and Mabel Beckman Center at the Chemical Heritage Foundation for providing research grants to support this project.

1. 3 THOMAS STARKIE, A PRACTICAL TREATISE ON THE LAW OF EVIDENCE, AND DIGEST OF PROOFS, IN CIVIL AND CRIMINAL PROCEEDINGS 1225–26 (London, J. & W. T. Clarke 1824).

2. *See, e.g.*, ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 74 (2004) (describing what can happen when the Patent Office "falls down on the job"); Jay P. Kesan & Andres A. Gallo, *Why "Bad" Patents Survive in the Market and How Should We Change?—The Private and Social Costs of Patents*, 55 EMORY L.J. 61, 61–76 (2006) (exploring criticisms); Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181–82 (2008) (same); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 689 (2004) ("The Patent Office . . . appears to grant many patents that, when carefully scrutinized, fail to meet basic patentability standards."); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 316–22 [hereinafter Thomas, *Collusion*] (exploring the patent quality crisis).

nonobvious, and clearly and sufficiently described."[3] Famous examples of questionable patents include one for a motorized ice cream cone,[4] an umbrella to protect beer cans from sunlight,[5] a method of exercising a cat with a laser pointer,[6] and a method for sending signals faster than the speed of light.[7] Aside from being technically invalid,[8] commentators have argued that such patents are worthless[9] and burdensome on the patent system.[10]

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3. R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009); *see also* JAFFE & LERNER, *supra* note 2, at 171 (presenting a similar definition). From an economic perspective, a high-quality patent is "one that covers an invention that would not otherwise be made [but for the incentive of a patent] or one that ensures that a good idea is commercialized . . . ." Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 991 (2004). The conditions for patentability are found in Title 35 of the United States Code. In short, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101–103 (2006). In addition, § 112 para. 1 requires that the application adequately describe, enable, and set forth the best mode contemplated for carrying out the invention; and § 112 para. 2 requires that the application conclude with claims that delineate the invention with particularity. 35 U.S.C. § 112 para. 1–2.

4. Motorized Ice Cream Cone, U.S. Patent No. 5,971,829 (filed Mar. 6, 1998).

5. Beerbrella, U.S. Patent No. 6,637,447 (filed Oct. 19, 2001).

6. Method of Exercising a Cat, U.S. Patent No. 5,443,036 (filed Nov. 2, 1993).

7. Hyper-Light-Speed Antenna, U.S. Patent No. 6,025,810 (filed Oct. 2, 1997). It is well accepted in science that a signal cannot travel faster than the speed of light. *See, e.g.*, ALBERT EINSTEIN & LEOPOLD INFELD, THE EVOLUTION OF PHYSICS 149 (1966) (explaining special relativity); Dennis Overbye, *Particles Faster Than the Speed of Light? Not So Fast, Some Say*, N.Y. TIMES, Oct. 25, 2011, at D3 (noting that despite recent claims to the contrary, physicists still agree with Einstein).

8. *See* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003) [hereinafter FTC REPORT] ("A poor quality or questionable patent is one that is likely invalid or contains claims that are overly broad.").

9. *See* Edmund W. Kitch, *Property Rights in Inventions, Writings, and Marks*, 13 HARV. J.L. & PUB. POL'Y 119, 122–23 (1990) ("[M]ost issued patents are worthless, or very nearly worthless."); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 603 (1999) ("[M]ost [patented] technologies will not be economically viable or commercially successful . . . .").

10. John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 731 (2002) [hereinafter Thomas, *Patent Administration Reform*] (explaining that legal actors must often revisit the Patent Office's work to assess patent validity).

The quality problem has been ascribed by different commentators to many different causes. For example, some assert that the Patent Office's current compensation system favors issuance over denial[11] and rewards throughput over thorough examination.[12] Perhaps most emblematic of this quality-compromising incentive structure is the Patent Office's self-declared mission to "help [its] customers get patents."[13] Others argue that examiners lack adequate technical information, such as access to the relevant prior art,[14] needed to perform a rigorous examination.[15] And others contend that the Patent Office's limited resources[16] (which contribute to the well-

11. *See, e.g.*, ANTHONY L. MIELE, PATENT STRATEGY 97–98 (2001) (discussing an examiner's concerns and incentives); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 945 (2004) (arguing that the skewed incentives of the current regime "make it easier and more desirable for examiners to grant patents rather than reject them"); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. REV. 1495, 1496 n.3 (2001) [hereinafter Lemley, *Rational Ignorance*] ("[E]xaminers must write up reasons for rejection, but not reasons for allowance, giving them more incentives to allow rather than reject an application.").

12. *See* Patrick A. Doody, *How to Eliminate the Backlog at the Patent Office*, 37 AIPLA Q.J. 395, 409–18 (2009) (describing examiners' incentives and production goals); Lemley, *Rational Ignorance*, *supra* note 11, at 1496 n.3 (describing the push for examiners to issue patents irrespective of quality).

13. *See* U.S. PATENT & TRADEMARK OFFICE, A PATENT AND TRADEMARK OFFICE REVIEW: CREATING A PATENT AND TRADEMARK SYSTEM FOR THE 21ST CENTURY, FISCAL YEAR 1997, at 8 (1997) (internal quotation marks omitted). For criticisms, see Lemley, *Rational Ignorance*, *supra* note 11, at 1496 n.3 ("While the job of the PTO is certainly to issue good patents, it is also to reject bad ones."); Jonathan S. Masur, *Costly Screens and Patent Examination*, 2 J. LEGAL ANALYSIS 687, 692–93 (2010) (arguing that this mission sets the stage for inadequate screening of patent applications).

14. "Prior art" refers to preexisting knowledge and technology already available to the public. *See* 35 U.S.C. § 102 (2006) (defining the documents and activities that can serve as prior art); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966)). The invention is compared to the prior art in assessing novelty and nonobviousness. *See infra* notes 160–61. *But see* Christopher A. Cotropia et al., *Do Applicant Patent Citations Matter? Implications for the Presumption of Validity* 12 (Stanford Law & Econ. Olin, Working Paper No. 401, 2012), *available at* http://ssrn.com/abstract=1656568 (finding through an empirical study that "examiners focus almost exclusively on art they find themselves [as compared to art provided by the applicant] in considering whether a patent application is new and nonobvious").

15. *See infra* note 285 and accompanying text.

16. *See infra* notes 28, 295 and accompanying text.

publicized backlog)[17] preclude a thorough review of applications.[18]

Yet, it would be unfair to cast all of the blame for failings in patent examination on the Patent Office. Several commentators have long argued that the substantive standards of patentability are too low.[19] Or, put simply, it is too easy to get a (bad) patent.[20] This criticism deserves attention because adjusting these standards is considered the principal tool for modulating the scope, frequency, and quality of patents.[21] Indeed, tightening the standards of patentability has been a major goal of judicial efforts at patent reform.[22] In a series of landmark de-

17. *See, e.g.*, Edward Wyatt, *U.S. Sets 21st-Century Goal: Building a Better Patent Office*, N.Y. TIMES, Feb. 21, 2011, at A1 (providing backlog statistics and partly attributing the recent surge in applications to the Internet age). One cause for the backlog is an increase in the number of patent application filings over time while the time available for examiners to review applications has remained constant. *See* John L. King, *Patent Examination Procedures and Patent Quality*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 54, 63 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (presenting an empirical study).

18. Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 46 (2007).

19. *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 162–63 (2008) (exploring the decline in patent quality and attributing the weakening of patentability standards to the Federal Circuit); JAFFE & LERNER, *supra* note 2, at 11 (noting that weak novelty and nonobviousness standards have led to patents of dubious quality).

20. *Cf.* Adam B. Jaffe, *Patent Reform: No Time Like the Present*, 4 I/S: J.L. & POL'Y FOR INFO. SOC'Y 59, 59 (2008) ("Changes in patent law and practice in the last two decades have made the system less effective, by making it too easy to get patents on trivial and non-original ideas . . . ."); Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J. L. SCI. & TECH. 1, 15 (2007) ("One of the most pressing problems in the patent system today is not that patents in general are too easy to obtain or too easy to enforce; rather it is that bad patents are too easy to obtain and enforce.").

21. *See, e.g.*, DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 142 (2009) (using the biotechnology industry to demonstrate the benefits of tailored standards). Admittedly, the term "quality" can be an ambiguous or normatively laden term. This Article uses a consistent definition throughout. *See supra* text accompanying note 3.

22. Patentability standards evolve primarily through judicial rather than legislative action. *See* John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 544 (2010) (explaining that patent law "has traditionally had a common law feel to it" because the courts receive little guidance from statutory sources); Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1243–44 (1994) (explaining that the "general" nature of the patent statutes requires the Federal Circuit to "unavoidably fill[] in gaps and develop[] fine points"); Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) (noting that the common law is "the dominant legal force in the development of U.S. patent law").

cisions, reform-minded courts have trimmed the scope of patent-eligible subject matter,[23] made it harder to obtain (and easier to invalidate) patents based on a lack of nonobviousness,[24] and reinvigorated the requirement that applicants provide an adequate disclosure of the invention.[25]

Thus, it appears that raising the substantive standards of patentability could go a long way toward solving the quality problem. For instance, if the standards are sufficiently high, an applicant would have a decreased likelihood of getting a patent. This might deter some persons from filing applications altogether because a robust examination would provide a disincentive for those with low-quality inventions to file.[26] Ultimately this would reduce the backlog, alleviate the overall strain on Patent Office resources, and (combined with various changes within the agency)[27] empower the examiner to conduct an even more robust examination of docketed applications. All of this

23. Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (holding that claims relating to a method of hedging risks are unpatentable).

24. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit's rigid test for nonobviousness due to its inconsistency with the "expansive and flexible approach" set forth in Supreme Court precedent).

25. *See, e.g.*, ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940–41 (Fed. Cir. 2010) (reiterating that an applicant must provide a disclosure which enables a person having ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351–53 (Fed. Cir. 2010) (en banc) (reaffirming well-settled law that an applicant must provide a disclosure showing possession of the full scope of the claimed subject matter).

26. "To put it crudely, if the [P]atent [O]ffice allows bad patents to issue, this encourages people with bad applications to show up." JAFFE & LERNER, *supra* note 2, at 175. On the other hand, a robust regime does the opposite because inventors "would understand that [low-quality] applications are a waste of time and money." *Id.* It is possible that high patentability standards could push some potential inventors into the realm of trade secret. Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 780 (2009) [hereinafter Cotropia, *Inequitable Conduct*] (citing John E. Calfee & Richard Craswell, *Some Effects of Uncertainty on Compliance with Legal Standards*, 70 VA. L. REV. 965, 981–82 (1984)).

27. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, 2010–2015 STRATEGIC PLAN 10–25 (2010), *available at* http://www.uspto.gov/about/stratplan/USPTO_2010-2015_Strategic_Plan.pdf (describing several initiatives that will improve examination timelines and patent quality); Press Release, U.S. Patent & Trademark Office, Recently Announced Changes to USPTO's Examiner Count System Go into Effect (Feb. 18, 2010), *available at* http://www.uspto.gov/news/pr/2010/10_08.jsp (announcing changes to the examiner count system which will give examiners more time to review applications, rebalance incentives, and improve morale in the examining corps).

would, at least in theory, improve the quality of issued patents.[28]

Yet, this is only part of the story. Irrespective of the substantive standards of patentability, *procedural* aspects of patent examination tip the scales in favor of issuance.[29] An applicant enjoys a presumption of patentability,[30] which means that at the time of filing the application is rebuttably presumed to comply with the utility, novelty, nonobviousness, and disclosure requirements of the patent statute.[31] Thus, the Patent Office *must* issue a patent unless it can affirmatively prove that the invention is unpatentable.[32] The scales tip even further toward issuance if the examiner lacks the time, materials, or incentives to conduct a high-quality examination.[33] And even though the applicant owes a duty of candor to the Patent Office,[34] no one actually believes that everything that the applicant knows about the invention ends up before the examiner.[35] Of course, this information deficit inevitably allows bad patents to slip through the cracks and further contributes to the patent quality problem.[36] The bottom line is that anyone who files a patent application on *anything* starts off in a very good position.[37] This

28. *See* Hall & Harhoff, *supra* note 3, at 993–94 (describing the interrelationship between Patent Office resources, filing frequency, and the examination of individual applications on patent quality).

29. *Cf.* FTC REPORT, *supra* note 8, Executive Summary, at 8 ("A plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application is filed.").

30. A presumption is an assumption that must be drawn by the decisionmaker in the absence of rebuttal evidence. 9 JOHN HENRY WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 2491, at 305 (John H. Chadbourn ed., rev. ed. 1981) [hereinafter WIGMORE ON EVIDENCE].

31. *See infra* Part II.A.

32. *See infra* Part II.A.

33. *See* sources cited *supra* note 12; BURK & LEMLEY, *supra* note 21, at 23 ("[A]n examiner has no incentive to spend more time on harder cases."); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 109 (2006) ("[T]he constraints of time, information, and evidentiary standards create a situation where '[t]he PTO's evaluation of a patent [application] may be so poor or hurried as to be near meaningless.'" (quoting Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 667–68 (2002))); Carl Shapiro, *Patent System Reform: Economic Analysis and Critique*, 19 BERKELEY TECH. L.J. 1017, 1019 (2004) (noting that patent examination is "tilted in favor of patent applicants").

34. *See infra* note 131 (discussing 37 C.F.R. § 1.56(a) (2012)).

35. *See infra* notes 129–31, 285 and accompanying text.

36. *See* sources cited *supra* note 3; sources cited *infra* note 285.

37. *Cf.* FTC REPORT, *supra* note 8, ch. 5, at 9 n.61 ("[P]atent applicants are in a really great position because by filing an application they're presump-

strongly suggests that any plan to improve patent quality must confront the powerful role that the presumption of patentability plays in patent examination.[38]

This Article is the first to take a hard look at the presumption of patentability.[39] Aside from comprehensively exploring its origins, contours, proffered rationales, and continued viability, this Article offers an alternative paradigm which better promotes the broader policy objectives of the patent system. It fills a gap in patent scholarship and will hopefully contribute to ongoing debates over patent reform.

The Article proceeds as follows. Part I describes the presumption of patentability and current allocations of burdens of proof and explores several legal and expediential justifications for the paradigm. Part II argues that negative externalities arise from the current paradigm's pro-applicant, pro-patent bias, and that these externalities hinder patent reform efforts and impede the patent system's overarching goal to promote scientific and technological progress. Finally, Part III sets forth a new paradigm which rebalances the scales of patentability. After describing the restructured evidentiary framework for patent examination, this Part offers a normative analysis of the new paradigm and explores its policy implications.

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tively entitled to receive the grant." (quoting Professor John R. Thomas)); Lemley & Sampat, *supra* note 2, at 192 (estimating that over 70% of applications eventually issue as patents); Dennis Crouch, *USPTO Grant Rates by Technology Center*, PATENTLY-O (May 27, 2010, 2:24 AM), http://www.patentlyo.com/patent/2010/05/uspto-grant-rate-by-technology-center.html (finding grant rates ranging from approximately 45%–80%, depending on the technology).

38. *See* FTC REPORT, *supra* note 8, ch. 5, at 9–10, 28 (identifying the presumption of patentability as one of the failings of ex parte patent examination); Leslie, *supra* note 33, at 108 ("Evidentiary standards provide an additional obstacle to PTO examiners denying patent applications.").

39. It is important to note that the presumption of patentability is not the same as the presumption of validity which attaches to issued patents. *See* 35 U.S.C. § 282 (2006) (codifying the presumption of validity); Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2251–52 (2011) (reaffirming that the presumption of validity can only be overcome with clear and convincing evidence). There is a robust body of scholarship on the latter. *See, e.g.*, Lichtman & Lemley, *supra* note 18.

I. UNDERSTANDING THE PRESUMPTION

A. THE CURRENT PARADIGM

Patent examination is an ex parte proceeding between the Patent Office examiner and the applicant.[40] Driving it are evidentiary mechanisms which include presumptions and shifting burdens of proof.[41] The current paradigm emerged from centuries-old Patent Office practices,[42] later buttressed by decisional law from the U.S. Court of Customs and Patent Appeals (C.C.P.A.)[43] and its successor court, the U.S. Court of Appeals for the Federal Circuit.[44]

The basic tenet of patent examination is that an applicant is entitled to a patent unless the Patent Office can prove otherwise.[45] The corollary is that a patent application presumptively complies with the statutory patentability requirements when it is filed—including utility, novelty, nonobviousness, and adequate disclosure of the invention.[46] Thus, the burden of proving unpatentability rests with the Patent Office.[47]

Working in tandem with the presumption is a burden-shifting framework which allocates the burden of proof between the examiner and the applicant. If it appears that the invention

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40. *See generally* ALAN L. DURHAM, PATENT LAW ESSENTIALS § 5.1 (3d ed. 2009) (explaining the process).

41. *Id.*

42. *See infra* Part I.B.1.

43. The C.C.P.A. was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. *See* GILES S. RICH, A BRIEF HISTORY OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS 1–2 (1980).

44. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. *See* Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal Circuit adopted the C.C.P.A. decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

45. *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent."); FTC REPORT, *supra* note 8, ch. 5, at 8–9 (explaining that the Patent Office must issue a patent unless it proves unpatentability, thereby effectively creating a presumption that every requested patent should issue).

46. *See* FTC REPORT, *supra* note 8, ch. 5, at 9–10 (exploring the consensus on this issue).

47. *Oetiker*, 977 F.2d at 1445 ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant."); *accord In re* Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (explaining that an examiner must affirmatively prove unpatentability).

does not satisfy a patentability requirement, the examiner has the initial burden of building and presenting a prima facie case of unpatentability.[48] It is established when

> the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with [what is described in the patent application], and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.[49]

The type of proof required to make a prima facie case depends on the statutory provision at issue. But, as a general matter, the examiner satisfies its initial burden by "adequately explain[ing] the shortcomings [he or she] perceives so that the applicant is properly notified and able to respond."[50] If this burden is met,[51] the burden of production shifts to the applicant to rebut the examiner's contention of unpatentability with persuasive argument or proof.[52] When the applicant submits rebuttal evidence, the examiner must "start over"[53] and "consider all of the evidence anew."[54] The burden of production may continue to shift as each side presents new evidence; however, the examiner carries the ultimate burden of persuasion.[55] The examiner must determine patentability based on the entire record,[56] with

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48. *Oetiker*, 977 F.2d at 1445; *In re* King, 801 F.2d 1324, 1327 (Fed. Cir. 1986) (noting that the Patent Office must establish a prima facie case before any burden shifting occurs).

49. 37 C.F.R. § 1.56(b)(2) (2012).

50. Hyatt v. Dudas, 492 F.3d 1365, 1370 (Fed. Cir. 2007).

51. It is worth noting that if the examiner fails to establish a prima facie case, the applicant need not provide any rebuttal evidence and is entitled to a patent barring other grounds for unpatentability. *In re* Dillon, 919 F.2d 688, 710 (Fed. Cir. 1990) (en banc) (citing *In re* Seigneurin, 474 F.2d 1020, 1023 (C.C.P.A. 1973) (explaining that since no prima facie was established, "[t]hat concludes the matter")).

52. *Oetiker*, 977 F.2d at 1445.

53. *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (citing *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A 1976)).

54. *Id.*

55. *Oetiker*, 977 F.2d at 1449; *see In re* Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) (articulating the rule that the Patent Office carries the burden of persuasion in showing why an applicant should not receive a patent).

56. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.05 (8th ed., rev. 8, 2010) [hereinafter MPEP] (instructing the examiner to evaluate enablement based on the weight of all the evidence, including any new evidence supplied by the applicant to rebut the prima facie case); *id.* § 716.01(d) (giving a similar instruction for the nonobviousness analysis).

a preponderance of the evidence as the standard of proof.[57] Absent any other grounds of unpatentability, the Patent Office must issue the patent.[58]

To illustrate the current framework, consider the following hypothetical. Suppose an inventor develops a method for making bread with the highly-publicized fat substitute Olestra.[59] Since Olestra is not available for retail purchase,[60] the inventor develops the method by replacing the fat and a portion of the flour in a white bread recipe with pulverized Lay's Light Original Potato Chips (which are fried in Olestra).[61] When the modified recipe yields an excellent loaf, the inventor prepares a patent application.[62] Although the application's written description[63] only discloses a single working example (the modified white bread recipe), it states that the amount of potato chips and flour needed in other embodiments[64] of the invention

57. *Oetiker*, 977 F.2d at 1445; *In re* Caveney, 761 F.2d 671, 674 (Fed. Cir. 1985) ("[P]reponderance of the evidence is the standard that must be met by the PTO in making rejections.").

58. *Oetiker*, 977 F.2d at 1445; Michel, *supra* note 22, at 1249 ("If the claimed invention is patentable, the applicant is *entitled* to a patent (because [§ 102 of] the statute says so)—not eventually, but as soon as patentability can be determined.").

59. *See, e.g.*, Marian Burros, *U.S. Approves Fake Fat for Use in Snack Foods*, N.Y. TIMES, Jan. 25, 1996, at A12; Dana Canedy, *Fat-Free Fanfare as Procter Starts Shipping Out Olestra*, N.Y. TIMES, Feb. 11, 1998, at D2. Olestra is an indigestible, fat-like molecule derived from sugar and vegetable oil accidentally discovered by Procter & Gamble researchers around 1968. Vivienne V. Yankah & Casimir C. Akoh, *Zero Energy Fat-Like Substances: Olestra*, *in* STRUCTURED AND MODIFIED LIPIDS 511, 514–15 (Frank D. Gunstone ed., 2001). It is a zero-calorie, non-fat oil, butter, and shortening substitute which tastes like fat. *Id.*; *see also* DAVID E. NEWTON, FOOD CHEMISTRY 82 (2007).

60. Currently Olestra is only available as an ingredient in certain snack foods. *See* Olestra, 21 C.F.R. § 172.867(c) (2012).

61. *See Lay's Light Original Potato Chips*, FRITO LAY, http://www.fritolay.com/our-snacks/lays-light-original.html (last visited Nov. 29, 2012) (listing ingredients).

62. For examples of patents directed to methods of making bread with fat substitutes, see Process for Producing a Fat-Substitute Bakery Dough and the Fat Substitute Bakery Products, U.S. Patent No. 5,344,663 (filed Jan. 15, 1992); Methods of Making Bread Products Without Shortenings and/or Oils, U.S. Patent No. 5,510,136 (filed Oct. 21, 1994).

63. The written description is the part of the patent (or patent application) that completely describes the invention. *See* 35 U.S.C. § 112 (2006) ("The specification shall contain a written description . . . . It shall conclude with one or more claims . . . ."). Although I will not do so in this Article, it is worth noting that the terms "written description" and "specification" are often used interchangeably (and mistakenly) in patent law. F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 155 n.4 (5th ed. 2011).

64. An "embodiment" is a concrete, physical form of an invention de-

can be determined empirically to produce various types of leavened and unleavened bread items such as other white breads, whole wheat breads, rye breads, buns, cinnamon rolls, breadsticks, pizza crusts, flour tortillas, and flatbreads.[65] The application concludes with the following claim:

> A method of making bread products without using shortenings and/or oils comprising: substituting pulverized Olestra-based potato chips for said shortenings and/or oils in a bread dough which is baked to make bread products.[66]

In patent law, this is considered a "broad" claim because the language does not limit the invention to any specific type of bread.[67]

An examiner with expertise in the field reads the application and checks it for compliance with the statutory patentability requirements.[68] Focusing on enablement, the question is whether a person having ordinary skill in the art (PHOSITA)[69] could make and use the invention as broadly as it is claimed at the time of filing without undue experimentation.[70] Analyzing enablement is a fact-intensive inquiry which includes construing the claim to determine its scope,[71] evaluating the teaching

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scribed in a patent application or patent. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 27 (5th ed. 2011).

65. *Cf.* '663 Patent col.15; '136 Patent col.3.

66. *Cf.* Claim 1, '136 Patent col.6 (making analogous claim that waxy barley flour can be substituted for shortenings and oils in bread dough).

67. *See* MIELE, *supra* note 11, at 98 (explaining an applicant's incentive "to obtain very broad claims for which a colorable argument can be made for patentability").

68. *See supra* note 3 (reciting the conditions for patentability).

69. The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987) (explaining that a PHOSITA is "not unlike the 'reasonable man' and other ghosts in the law"). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made. Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983) (listing the factors).

70. *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Although the term "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation." *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

71. *See* MPEP, *supra* note 56, § 2164.04 (instructing examiners to construe claims before analyzing enablement). Claim construction includes defining terms that are ambiguous or are not well known in the art, while simulta-

provided in the written description, and determining the PHOSITA's knowledge and level of skill.[72]

The examiner rejects the claim as prima facie nonenabled.[73] Relying on a reference[74] which describes the "complex" nature of baking,[75] the examiner concludes that a PHOSITA could not read the applicant's description about the single embodiment actually made (white bread) and extrapolate from it how to make without difficulty other embodiments encompassed by the claim (the universe of bread products).[76] And since the reference explains that bread quality is highly dependent on the identity and quantity of flour, fat, and other

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neously giving the claims the broadest reasonable interpretation consistent with the written description. *In re* Bass, 314 F.3d 575, 577 (Fed. Cir. 2002).

72. *Cf.* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) ("[W]ith respect to enablement[,] the relevant inquiry lies in the relationship between the [written description], the claims, and the knowledge of one of ordinary skill in the art."). The Federal Circuit has articulated a nonexhaustive list of factors—the so-called *Wands* factors—for determining undue experimentation, including (1) the amount of direction or guidance presented in the disclosure; (2) the existence of working examples; (3) the nature of the invention; (4) the predictability or unpredictability of the art; (5) the PHOSITA's relative skill; (6) the state of the prior art; (7) the breadth of the claims; and (8) the quantity of experimentation necessary to practice the claimed invention. *Wands*, 858 F.2d at 737. Certain factors may be more relevant than others for a particular invention. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the *Wands* factors are illustrative and not mandatory).

73. To establish a prima facie case of nonenablement, the examiner must set forth a reasonable explanation as to why he or she believes that the scope of protection sought in that claim is not adequately enabled by the description of the invention provided in the written description. *Wright*, 999 F.2d at 1561–62.

74. The examiner must support rejections with references. *In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971); *see also In re* Brebner, 455 F.2d 1402, 1405 (C.C.P.A. 1972) (holding that the Patent Office must provide a factual basis for a lack of enablement rejection, rather than conclusory statements as to the level of ordinary skill in the art).

75. "Bread quality is determined by the complex interactions of the raw materials, their qualities and quantities used in the recipe and the dough processing method." Stanley P. Cauvain, *Breadmaking: An Overview*, *in* BREAD MAKING: IMPROVING QUALITY 8, 14 (Stanley P. Cauvain ed., 2003).

76. Whether a single working example is sufficient to enable a broad claim is a quintessential enablement issue. *Compare In re* Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944) (explaining that an inventor "is generally allowed [broad] claims, when the art permits, which cover more than the specific embodiment shown" (emphasis omitted)), *with* Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (determining that a disclosure that enabled one embodiment was insufficient to support a claim that covered additional embodiments).

ingredients,[77] the examiner concludes that a PHOSITA would have to engage in undue experimentation to practice the full scope of the claimed invention.[78]

The applicant responds with three rebuttal arguments. First, the applicant points out that the claim makes no mention of the *quality* of the bread product; thus any rejection relating to bread quality is improper.[79] Second, the applicant reminds the examiner that to satisfy enablement, one can rely on what is taught in the patent document as well as what the PHOSITA already knows or could figure out through routine experimentation.[80] Third and relatedly, the applicant argues that experimentation that is laborious, tedious, time-consuming, or requires the manipulation of multiple variables is not necessarily undue—particularly if it is routine or the nature of the art so demands.[81] The applicant bolsters this argument with a book[82]

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77. Cauvain, *supra* note 75, at 14–17.

78. *See supra* notes 70, 72 (describing the "without undue experimentation" requirement for enablement).

79. *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (explaining that enablement only focuses on what is actually claimed, but noting in dicta that an invention's imperfect or crude operation does not defeat patentability).

80. AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the [PHOSITA's] knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art."). *But see* ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940–41 (Fed. Cir. 2010) ("[T]he rule that a specification need not disclose what is well known in the art is merely a rule of supplementation, not a substitute for a basic enabling disclosure . . . . To satisfy the plain language of § 112 para. 1, [an applicant] cannot simply rely on the knowledge of [the PHOSITA] to serve as a substitute for the missing information in the specification." (internal citations and quotation marks omitted)).

81. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *In re* Jackson, 217 U.S.P.Q. (BNA) 804, 807 (Bd. App. 1982) ("The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . . .")); *see also* Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998) (finding that repeating experiments to obtain success is not undue experimentation); *In re* Angstadt, 537 F.2d 498, 502–03 (C.C.P.A. 1976) (explaining that since limiting claim scope to embodiments actually made has downsides for patent policy, the unfortunate consequence is that a PHOSITA must engage in time-sensitive experimentation to figure out what works).

82. PAULA FIGONI, HOW BAKING WORKS: EXPLORING THE FUNDAMENTALS OF BAKING SCIENCE 480–81 (3d ed. 2011).

which teaches that using fat replacers in baking requires trial and error—a permissible type of experimentation.[83]

Upon reconsideration, after weighing all of the evidence, the examiner acquiesces and withdraws the enablement rejection.[84] Absent other grounds for unpatentability, the application proceeds to patent issuance.[85]

B. LEGAL JUSTIFICATIONS

1. Patent Office Practices

History reveals that placing the ultimate burden of proving unpatentability with the examiner has been an established practice in the Patent Office for over a century. The principal cited authorities are a pair of old Patent Office rules and an intraoffice appeal from 1900 involving a paper fastener and a recalcitrant examiner.[86] The first rule required the examiner to state the grounds for rejection with specificity.[87] The second rule required the examiner to reconsider patentability if the applicant challenged a rejection, giving due care to the applicant's arguments.[88] In the appeal, *Ex parte Garms*,[89] the examiner had rejected a claim for a paper fastener for a lack of novelty based on the examiner's personal knowledge of the subject matter. The second rule mentioned above required the examiner to support a personal-knowledge rejection with an affidavit

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83. W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1557 (Fed. Cir. 1983) (citing Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270–71 (1916) ("leaving something to the skill [of the PHOSITA]" was sufficient for patentability because it was impossible for the patentee to disclose the precise, most successful treatment for each embodiment)).

84. Once the applicant provides rebuttal evidence, the examiner "must then weigh all the evidence[,] including the specification and any new evidence supplied by [the] applicant with the evidence and/or sound scientific reasoning previously presented in the [initial] rejection and decide whether the claimed invention is enabled." MPEP, *supra* note 56, § 2164.05.

85. *See supra* note 58 and accompanying text.

86. *See* Leon Zitver, *The Resolution of Doubt*, 28 J. PAT. OFF. SOC'Y 389, 397–98 (1946) (exploring the history of placing the burden of proving unpatentability on the examiner).

87. *See* E. J. STODDARD, ANNOTATED RULES OF PRACTICE IN THE UNITED STATES PATENT OFFICE 226 (1920) (Rule 65, which explained that "[t]he reasons for the rejection will be fully and precisely stated"); *id.* at 231 (Rule 66, which required the examiner to explain the pertinency of an asserted reference).

88. *See id.* at 226 (Rule 65).

89. 93 Off. Gaz. Pat. Office 190 (1900).

(which the applicant could attack).[90] The examiner refused to furnish an affidavit despite the rule and the applicant's repeated requests.[91] On appeal, the Commissioner of Patents scolded the examiner for his stubbornness and granted a petition to compel him to comply with the rule.[92]

Reliance on these authorities as support for the allocation of the burden of persuasion has been criticized.[93] For instance, one commentator has argued that the authorities appear to have more to do with the (shifting) burden of producing evidence:

> The ultimate burden of proof is borne by the same party throughout a proceeding and is fixed by substantive law. The duty of producing evidence, that is, of going forward with the case, is a procedural matter and shifts back and forth between the parties as the proceedings advance. [The cited authorities] deal only with [this] burden. The ultimate burden of proof is a matter beyond the scope of the Patent Office Rules of Practice, which are procedural and not substantive in nature.[94]

Nevertheless, these authorities anchor the "long-established custom" of placing the burden of proving unpatentability on the examiner.[95]

Buttressing the presumption of patentability is the now-defunct "rule of doubt."[96] It required that all doubts as to patentability were to be resolved in favor of the applicant.[97] Attorney General William Wirt first articulated the rule in 1827: "In every case of doubt, however, it would seem to be more congen-

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90. When reference is made to facts within the personal knowledge of an employee of the office, the data shall be as specific as possible, and the reference must be supported, when called for, by the affidavit of such employee; such affidavit shall be subject to contradiction, explanation, or corroboration by the affidavits of the applicant and other persons.

STODDARD, *supra* note 87, at 232 (Rule 66 in pertinent part).

91. *Garms*, 93 Off. Gaz. Pat. Office at 190.

92. *Id.*

93. *See, e.g.*, Zitver, *supra* note 86, at 398.

94. *Id.* (citing WIGMORE ON EVIDENCE, *supra* note 30, §§ 2485–2489).

95. V. I. Richard, *Ex Parte Appeals to the Board of Appeals. Outline of Practice*, 25 J. PAT. OFF. SOC'Y 303, 303 (1943).

96. *In re* Hofstetter, 362 F.2d 293, 297–99 (C.C.P.A. 1966) (tracing the origins and evolution of the rule), *vacated*, Brenner v. Hofstetter, 389 U.S. 5, 5 (1967).

97. *Id.* For additional commentary, see W. Becker & S. Heller, *The "Rule of Doubt"—In re* Hofstetter, 49 J. PAT. OFF. SOC'Y 607 *passim* (1967); Edwin M. Thomas, *Resolving Doubts Regarding Patentability*, 20 J. PAT. OFF. SOC'Y 831 (1938); Zitver, *supra* note 86, at 397–98; Benjamin F. Lambert, Student Paper, *Patentability—Rule of Doubt*, 12 IDEA 703 *passim* (1968).

ial with the policy of the law to afford the citizen an opportunity of trying the validity of his right by issuing the patent."[98]

The rule had become firmly entrenched within the agency by the end of the nineteenth century[99] and was widely applied by the courts hearing ex parte appeals from the Patent Office[100] for most of the twentieth century.[101] In *In re Hofstetter*,[102] the C.C.P.A. proffered "very sound policy reasons"[103] for the rule:

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98. 2 Op. Att'y Gen. 52, 52 (1827).

99. This occurred after several twists and turns. *Compare Ex parte* Coes, 6 Off. Gaz. Pat. Office 1, 1 (1874) (explaining that giving the applicant the benefit of the doubt in all cases can result in the issuance of "frivolous patents"), *with Ex parte* Fanshawe, 57 Off. Gaz. Pat. Office 1127, 1128 (1891) (noting that when a comparison of the claimed device and the prior art raises a doubt as to patentability, the doubt should be resolved in favor of the applicant).

100. Beginning in 1927, an applicant whose claims had been rejected by the examiner could appeal to an intraoffice tribunal known as the Board of Appeals. *See* P. J. Federico, *Evolution of Patent Office Appeals (Part II)*, 22 J. PAT. OFF. SOC'Y 920, 944–45 (1940). The U.S. Court of Appeals for the District of Columbia Circuit exercised exclusive jurisdiction over ex parte appeals from the Patent Office until 1929. *See* Act of July 8, 1870, ch. 230, § 48, 16 Stat. 198, 205 (repealed 1929). At that time, jurisdiction was transferred to the C.C.P.A. *See* Act of March 2, 1929, ch. 488, §§ 1–2, 45 Stat. 1475, 1475–76; RICH, *supra* note 43, at 1. Alternatively, a disgruntled applicant who wanted to introduce additional evidence could file a civil action with the U.S. District Court for the District of Columbia. *See* 35 U.S.C. §§ 141, 145 (2006). Prior to the creation of the Federal Circuit in 1982, appeals in civil actions remained with the D.C. Circuit. *See* Federico, *supra*, at 947. In sum, three appellate courts—the D.C. Circuit, C.C.P.A., and Federal Circuit—have heard appeals from the Patent Office.

101. *See, e.g.*, *In re* Eastwood, 33 App. D.C. 291, 299–300 (D.C. Cir. 1909) ("[When it is] a doubtful question whether appellant's discovery is not patentable . . . it has been the policy of this court to resolve the doubt in favor of the applicant." (citing *In re* Thompson, 26 App. D.C. 419, 425 (D.C. Cir. 1906)); *In re* Sporck, 301 F.2d 686, 690–91 (C.C.P.A. 1962) (explaining that when there is a doubt as to the factual basis supporting the Board of Appeals' conclusion of obviousness, "the doubt should be resolved in favor of the applicant"); *In re* Hummer, 241 F.2d 742, 746 (C.C.P.A. 1957) ("We think any doubt on the question of patentability should be resolved in favor of the applicant."); *In re* Uddenborg, 39 F.2d 710, 713 (C.C.P.A.1930) ("[T]he appellant has produced a new device which accomplishes a new and useful purpose and . . . the spirit and purpose of the patent law will be subserved by the grant of a patent to him. If there is any doubt about it, he should have the benefit of it." (citations omitted)). The C.C.P.A. explained how the rule worked when applied in appellate proceedings:

> It was that if the court, *after* consideration of *everything* made available to it by the record, was left in doubt about patentability (on any ground), such ultimate doubt should be "resolved" in favor of the applicant for patent. To state it another way, the applicant was "given the benefit" of the doubt.

In re Naber, 503 F.2d 1059, 1060 (C.C.P.A. 1974) (per curiam).

> Several of the factors properly taken into account in determining patentability, specially unobviousness and utility, are often not known at the time when the application is being prosecuted in the Patent Office but are developed later, perhaps even after the patent is issued. *It therefore is proper that doubt should be resolved in favor of applicants* so that they shall not be denied patents which later events may show them entitled to. Among such events, which may even have to await patenting, are commercial success, unexpected utility, displacement of competing devices, etc.[104]

Thus, the rationale behind the rule "was that patents are often granted with a view toward leaving open, to be decided by the courts, questions which the Patent Office does not deem it proper to adjudicate against the applicant by withholding the patent."[105] Though the C.C.P.A. believed that the rule "ma[de] for a better and fairer . . . patent system,"[106] the Supreme Court ultimately rejected this reasoning.[107]

While the rule of doubt was ultimately abandoned by the Patent Office[108] and the courts,[109] the ultimate burden of proving unpatentability with the examiner has remained intact.[110]

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102. 362 F.2d 293 (C.C.P.A. 1966), *vacated*, Brenner v. Hofstetter, 389 U.S. 5 (1967).

103. *Id.* at 298.

104. *Id.* (emphasis added); *cf.* 1 R. CARL MOY, MOY'S WALKER ON PATENTS § 3:17 (4th ed. 2012) (contending that "the USPTO's substantive determination of patentability is simply an initial determination of whether the applied-for patent right appears likely to survive challenge before the courts" and that the agency's determination "is less complete than the judicial determination of validity" (citing U.S. Patent Office, *Study No. 25: Court Decisions as Guides to Patent Office Policy and Performance*, *in* STAFF OF S. COMM. ON THE JUDICIARY, 86TH CONG., 2D. SESS., STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHTS (Comm. Print 1960) (written primarily by George C. Roeming))).

105. Lambert, *supra* note 97, at 706–07. The D.C. Circuit proffered a similar rationale:

> In case of ordinary doubt, the policy of the patent system, as customarily maintained in the Patent Office, has been to give the applicant the benefit thereof, because no absolute right of property is conferred by the grant of a patent. The patentee is merely put in a position to assert his prima facie right against infringers who may, in their defense, raise the question of the validity of the patent, and have the same finally adjudicated in the light of a full presentation and consideration of all the evidence attainable in respect of anticipation, prior knowledge, use, and the like.

Thompson, 26 App. D.C. at 425 (internal citation omitted).

106. *Hofstetter*, 362 F.2d at 298.

107. *See* Graham v. John Deere Co., 383 U.S. 1, 18 (1966) ("[I]t must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office. To await litigation is—for all practical purposes—to debilitate the patent system.").

108. Edward J. Brenner, Comm'r of Patents, Patent Office Activities Dur-

2. Statutory Considerations

Another justification for the presumption of patentability comes from language in the Patent Act. Those who espouse this view point specifically to the introductory clause of § 102 of Title 35 of the U.S. Code which states that "a person shall be entitled to a patent unless . . . ."[111]

Since § 102 deals with novelty, on its face the language seems to create a presumption of novelty. The C.C.P.A. recognized as much in *In re Wilder*.[112] Yet the Federal Circuit has construed the language in that provision much more broadly to compel the Patent Office to demonstrate unpatentability for *any* of the patentability criteria.[113] One possible justification for

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ing Fiscal Year 1966—Outlook for Fiscal Year 1967, Address Delivered to Patent Office Professional Staff (July 28, 1966), *in* 48 J. PAT. OFF. SOC'Y 475, 476 (1966) ("In order to further clarify Office policy . . . I wish to state here that it is our judgment that any application covering an invention of doubtful patentability should not be allowed, unless and until such doubt is removed in the course of examination and prosecution . . . .").

109. *See In re* Andersen, 743 F.2d 1578, 1580 (Fed. Cir. 1984) ("[T]he premise that doubts as to patentability should be resolved in favor of a patent applicant is now defunct." (citation omitted)), *overruled in part by In re* Etter, 756 F.2d 852 (Fed. Cir. 1985); Reynolds v. Aghnides, 356 F.2d 367, 367 (D.C. Cir. 1966) (per curium) ("[D]oubt (as to patentability) is to be resolved, not in favor of the applicant, but in favor of the correctness of administrative action." (internal citation and quotation marks omitted)); Abbott v. Coe, 109 F.2d 449, 451 (D.C. Cir. 1939) ("While the judgment of Patent Office officials is not absolutely binding on the courts, it is entitled to great weight, and is to be overcome by clear proof of mistake." (citation omitted)); *id.* at 451 (noting further "[t]he presumption that the Patent Office is right"); *In re* Naber, 503 F.2d 1059, 1060 (C.C.P.A. 1974) (per curiam) (explaining that doubts as to obviousness in the case were resolved by the examination of facts and not "by any arbitrary rule"); *In re* Mixon, 470 F.2d 1374, 1378–79 (C.C.P.A. 1973) (Worley, C.J., supplemental opinion) (inviting the court to abandon the rule for the sake of judicial uniformity, certainty, and lack of statutory support).

110. *See supra* Part I.A.

111. 35 U.S.C. § 102 (2006).

112. 429 F.2d 447, 450 (C.C.P.A. 1970) ("[T]he statute provides for what may be said to be a presumption of novelty in the language of section 102 'a person shall be entitled to a patent *unless* . . . .'" (emphasis added)).

113. FTC REPORT, *supra* note 8, ch. 5, at 8. In other words, as far as the presumption is concerned, the courts make no distinction between novelty and the other substantive requirements for patentability. *See* Tafas v. Doll, 559 F.3d 1345, 1364 (Fed. Cir. 2009) (noting that the district court's reliance on § 102 that "[a] person shall be entitled to a patent unless" combined with Federal Circuit precedent places the initial burden of proving unpatentability on the Patent Office (citing *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992))); FTC REPORT, *supra* note 8, ch. 5, at 8 n.56 (noting the breadth of the presumption as applied to all patentability criteria even though "the language relied upon, that a 'person shall be entitled to a patent unless' appears in § 102 of the Patent Act, dealing with novelty but not in § 103 (dealing with

this one-size-fits-all interpretation is that it would be unworkable for applicants, the Patent Office, and the courts to handle different and unique presumptions and proof burdens for each of the individual statutory patentability requirements.[114]

The Federal Circuit also points to the introductory clause of § 102 as support for the locution of the initial burden of producing evidence (of unpatentability) and the burden of persuasion.[115] As former Federal Circuit Chief Judge Paul Michel once explained:

> If the claimed invention is patentable, the applicant is *entitled* to a patent (*because the statute says so*)—not eventually, but as soon as patentability can be determined. Moreover, the burden of proof is on the PTO to show unpatentability, not on the applicant to establish patentability, and it remains on the PTO even if [it] has made a prima facie case.[116]

This expansive interpretation of the clause not only places an applicant in a very good position,[117] but also impedes attempts "to weed out unwarranted patents."[118]

The details of the clause's drafting history also suggest that the Federal Circuit is reading too much into it. The 1952 Patent Act was co-drafted by then-Examiner-in-Chief and Patent Office Board of Appeals member Pasquale J. (Pat) Federico[119] and then-patent attorney and future C.C.P.A. and Federal Circuit Judge Giles Sutherland Rich.[120] In a first-person account of the drafting of the clause, Judge Rich explained:

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nonobviousness) or § 112 (dealing with enablement, written description, best mode and utility)").

114. Thus, the Patent Office and the courts make no practical distinction between the different patentability criteria. *But see* Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech., 543 F.3d 657, 662 (Fed. Cir. 2008) (noting that while utility, patent-eligible subject matter, novelty, and nonobviousness are "conditions of patentability," the disclosure requirements of § 112 are "merely requirements for obtaining a valid patent").

115. *Cf.* FTC REPORT, *supra* note 8, Executive Summary, at 9 ("[T]he courts have interpreted the patent statute to require the PTO to grant a patent application unless the PTO can establish that the claimed invention does not meet one or more of the patentability criteria. Once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise.").

116. Michel, *supra* note 22, at 1249 (second emphasis added).

117. *See supra* notes 29–38 and accompanying text.

118. FTC REPORT, *supra* note 8, ch. 1, at 31–32.

119. For a short biographical sketch, see Giles S. Rich, *P. J. (Pat) Federico and His Works*, 64 J. PAT. OFF. SOC'Y 3, 3–11 (1982).

120. *See* Judge Giles S. Rich, C.C.P.A., Congressional Intent—Or, Who Wrote the Patent Act of 1952?, Lecture Presented at the First Annual Institute on Patent Law (Mar. 21–22, 1963), *in* PATENT PROCUREMENT AND EX-

> There is an interesting thing about the introductory clause of [section] 102. Pat originally wrote "An invention shall not be considered new or capable of being patented if . . . ." As the drafting progressed, taking a tip from the Lanham Act, section 2, we turned it into the positive statement "A person shall be entitled to a patent unless . . . ." as it reads today. We just felt like slapping down the detractors of the patent system, many of whom were in the judiciary.[121]

Given the drafters' motivation for the word choices, an expansive interpretation of the clause's language seems even more tenuous.

C. EXPEDIENTIAL ARGUMENTS

Since it is unlikely that Congress will tinker with the patent statutes any time in the foreseeable future,[122] any efforts to change the presumption of patentability or the current allocations of the burdens of proof will likely come from the Federal Circuit.[123] Though the court points to § 102 as primary support for its stance, it is perhaps buttressed by one or more expediential considerations.

1. Information Gathering

Patent procurement imposes a substantial information burden on the Patent Office. As Professor Lee Petherbridge has explained:

> The Patent Office has three primary information functions. Those functions include collection, use, and recordation. The Patent Office performs its "collection" function by (1) collecting information concerning the boundaries of the property for which an applicant seeks the right to exclude and (2) collecting information concerning the prior art [or other patently relevant factors]. The Patent Office performs

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PLOITATION 61, 67–69 (1963) (discussing the composition of the Drafting Committee for the bill that became the 1952 Patent Act).

121. Janice M. Mueller, *A Rich Legacy*, 14 BERKELEY TECH. L.J. 895, 902 (1999) (quoting an e-mail from Judge Giles S. Rich to Janice Mueller, Assoc. Professor, The John Marshall Law School (Aug. 8, 1997)). The original language appeared in the first bill introduced in Congress relating to what became the Patent Act of 1952, H.R. 9133, in 1950. The text was changed in a subsequent bill, H.R. 3760, introduced in the next congressional session. *Compare* H.R. 9133, 81st Cong. § 102 (2d Sess. 1950) ("An invention shall not be considered new or capable of being patented if . . . ."), *with* H.R. 3760, 82d Cong. § 102 (1st Sess. 1951) ("A person shall be entitled to a patent unless . . . .").

122. In 2011, Congress made the most sweeping reform to U.S. patent law since 1952. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

123. *See* sources cited *supra* note 22 (discussing the importance of the Federal Circuit in the development of U.S. patent law).

> its "use" function by engaging in the substantive decision making that attends the statutory requirements for patentability. The Patent Office performs its "recordation" function by (1) recording information useful for defining the boundaries of the property and (2) recording information that shows how the boundaries of the patented property make that property completely and patentably distinct from property already in the public domain.[124]

The collection and use functions in particular can be very information-demanding inquiries.[125] For example, the Federal Circuit has articulated eight factors which can be relevant in determining whether an applicant's disclosure satisfies the enablement requirement; including the state of the prior art and the PHOSITA's knowledge and level of skill.[126] Nonobviousness is also a highly fact-intensive inquiry which (like enablement) depends on the nature of the technology and the PHOSITA's knowledge and abilities.[127] The information demands of these multifactor inquiries intensify as the subject matter becomes more complex.[128]

Solving the information-gathering problem is not easy. For instance, providing examiners with more time to work on complex cases would at best provide an incomplete solution. As Professor Joseph Scott Miller has argued:

> [E]ven if the Patent Office were to invest far more in reviewing applications, its review would still suffer from a basic knowledge deficit compared to that which well-informed inventors and their competitors possess. Unlike these parties, the Patent Office is not actually

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124. Lee Petherbridge, *Positive Examination*, 46 IDEA 173, 189 (2006).

125. *See* Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 62–74 (2010) (exploring the information-demanding nature of the patentability requirements and the associated costs and externalities).

126. *See* discussion *supra* note 72 (discussing the test for enablement set forth in *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

127. Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911, 929 (2007). The nonobviousness requirement, embodied in § 103(a) of the Patent Act, denies patents for trivial extensions of what is already in the public domain. *See* John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 6–17 (2007) (exploring the wisdom of denying patents for trivial inventions). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court articulated the basic framework for determining nonobviousness. It is a question of law based on the following pertinent underlying facts: (1) the scope and content of the relevant prior art; (2) the differences between the prior art and the claimed invention; (3) the PHOSITA's level of skill; and (4) secondary considerations which provide objective proof of nonobviousness, such as commercial success or that the invention fulfilled a long-felt but unsolved need. *Id.* at 17.

128. *See* Lee, *supra* note 125, at 67.

> innovating on the leading edge of technological change in a given field.[129]

Applicants can do much to improve the information deficit because they "know better than [the Patent Office or] anyone else precisely what it is they have developed or invented . . . ."[130] The challenge is to get this knowledge into the examiner's hands.[131]

Though it is well known that the Patent Office has problems gathering adequate information,[132] so too does the Federal Circuit.[133] When the court adjudicates an ex parte appeal from the Patent Office, it receives a record which is limited to the prosecution history and proceedings before the Patent Office's Patent Trial and Appeal Board.[134] Unlike appeals from district courts, the Federal Circuit is precluded from the benefit of additional evidence or factfinding.[135] Combined with the fact that

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129. Miller, *supra* note 2, at 733.

130. *Id.* at 734.

131. The Patent Office seeks to combat its information deficit by imposing upon applicants "a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . . ." 37 C.F.R. § 1.56(a) (2012).

132. *See, e.g.*, Petherbridge, *supra* note 124, at 189; sources cited *supra* note 2; sources cited *infra* note 283.

133. *See* Petherbridge, *supra* note 124, at 189 (explaining that while the Patent Office can collect information from a wide array of sources, "the other participants in the patent system, *i.e.*, competitors, courts, and the public-at-large cannot").

134. 35 U.S.C. § 144 (2006) ("The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office."); *see also In re* Gartside, 203 F.3d 1305, 1314 (Fed. Cir. 2000) ("In appeals from the Board, we have before us a comprehensive record that contains the arguments and evidence presented by the parties . . . . That record, when before us, is closed . . . . [And] thus dictates the parameters of our review."); *In re* Varga, 511 F.2d 1175, 1178 (C.C.P.A. 1975) (explaining that § 144 limits the appeal to "evidence produced before the Patent Office"). Before passage of the America Invents Act in 2011, the tribunal was known as the Board of Patent Appeals and Interferences. *See* Leahy-Smith America Invents Act Pub. L. No. 112-29, § 3, 125 Stat. 284, 290 (2011) (eliminating interference proceedings).

135. *See* sources cited *supra* note 134; *In re* Jones, 10 F. App'x 822, 828–29 (Fed. Cir. 2001) ("This court is not a fact-finder in the first instance . . . . [O]ur review is limited to the record before the Board." (citing 35 U.S.C. § 144; *Gartside*, 203 F.3d at 1316)). To further explain the procedural aspects of patent appeals, an applicant whose claims have been twice rejected by the examiner can appeal to an intraoffice tribunal (Board) which, among other things, reviews adverse decisions of examiners. *See supra* notes 100, 134; 35 U.S.C. §§ 6(b), 134(a) (2006); Leahy-Smith America Invents Act, §§ 3, 7. The Board can affirm a rejection or reverse and remand to the examining corps. 37 C.F.R. § 1.197 (2012). An applicant dissatisfied with a Board decision can appeal to the Federal Circuit or file a civil action against the Director in federal district court. *See* 35 U.S.C. §§ 141, 145 (2006) (placing venue with the U.S.

the Patent Office all-too-often lacks adequate information about the invention at the time of examination,[136] it stands to reason that the Federal Circuit could face an information deficit when adjudicating an ex parte appeal.[137]

Viewed in this light, the current paradigm begins to make sense. The court imposes presumptions and allocates burdens of proof in such a way as to maximize the quantity of information generated during examination to hopefully ensure the production of a robust record for appeal.[138] In deciding whether the applicant or the Patent Office is in the best position to provide this information, the court seems to believe—and perhaps not unreasonably so (even if not rightly)—that requiring the Patent Office to both go first by building a prima facie case of unpatentability and to carry the burden of persuasion on the patentability issue is the best way to achieve this goal.[139]

2. Concerns About Arbitrariness and Competence

To the extent that the Federal Circuit views itself as the steward of the patent system[140] and as overseer of the Patent

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District Court for the District of Columbia); Leahy-Smith America Invents Act § 9(a) (amending § 145 by moving venue to the U.S. District Court for the Eastern District of Virginia). In the latter, the parties may submit additional evidence or argue the previous evidence afresh. Hyatt v. Kappos, 625 F.3d 1320, 1330–33 (Fed. Cir. 2010) (en banc) (reaffirming that the applicant's ability to introduce new evidence is the hallmark of a § 145 action and rejecting the Patent Office's contention that "the applicant is *only* allowed to introduce new evidence that 'the applicant could not reasonably have provided to the agency in the first instance'" (emphasis added)), *aff'd*, 132 S. Ct. 1690, 1700–01 (2012).

136. *See supra* note 132 and accompanying text.

137. *Cf.* Petherbridge, *supra* note 124, at 189 ("Because the record becomes fixed . . . how well the Patent Office performs its information functions is a rate limiting step in the patent system and thus allocates information costs to other participants.").

138. *See* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 817–18 (2011) (noting that the Federal Circuit's use of presumptions in the infringement context serves a "information-forcing" function).

139. Put simply, the court views the status quo as the most pragmatic way to get information in the ex parte appeal context. *See* Lee, *supra* note 125, at 77–79 (arguing that in contrast to district court judges who can conduct complicated factfinding and the Supreme Court which can take a "big picture" approach to patent cases, the Federal Circuit is primarily concerned with "everyday practicality").

140. *See* Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1797 (2011) ("[T]he Federal Circuit is in many ways the primary steward of substantive patent law."); Rebecca S. Eisenberg, Commentary, *The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*,

Office,[141] the court might have an interest in ensuring that the Patent Office is not making arbitrary patentability determinations. This explains, at least in part, why the Federal Circuit and its predecessor[142] have insisted that the Patent Office support determinations of unpatentability with factual evidence or sound technical reasoning[143] rather than with conclusory statements[144] or subjective judgments.[145]

Thus, it could be argued that the current proof paradigm exists simply to ensure fairness in patent examination. A different view is that it reflects skepticism about the Patent Office's technical competence.[146] At least for enablement and

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106 MICH. L. REV. FIRST IMPRESSIONS 28, 28 (2007), http://www.michiganlawreview.org/assets/fi/106/eisenberg.pdf (explaining that the Supreme Court "is free to grant certiorari [in patent cases] more often if it is unhappy with the Federal Circuit's stewardship").

141. *Cf.* Jeffrey A. Lefstin, *The Constitution of Patent Law: The Court of Customs and Patent Appeals and the Shape of the Federal Circuit's Jurisprudence*, 43 LOY. L.A. L. REV. 843, 892 (2010) (referring to the C.C.P.A.'s "role as overseer of the Patent Office"); Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1975 (2009) ("In addition to getting more autonomy from executive branch oversight, the PTO has also been trying to get more deferential review of its decisions from the Federal Circuit."); *id.* at 1982 ("[T]he framework used by the Federal Circuit to determine whether future PTO-proposed rules are procedural or substantive continues to allow the court to oversee the PTO.").

142. *See supra* note 43 (discussing the C.C.P.A.).

143. *See, e.g.*, *In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971) (noting that specific technical reasons are required to challenge enablement); *accord In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (applying *Marzocchi* to the utility context). The Federal Circuit has held that the Administrative Procedure Act, which governs Patent Office tribunals and the related judicial review, requires the agency to provide a record with full, reasoned, and well-articulated explanations for its conclusions. *In re* Sang-Su Lee, 277 F.3d 1338, 1342 (Fed. Cir. 2002) (citing Dickinson v. Zurko, 527 U.S. 150 (1999)).

144. *See In re* Brebner, 455 F.2d 1402, 1405 (C.C.P.A. 1972) (holding that the Patent Office must provide a factual basis for a lack of enablement rejection, rather than conclusory statements regarding the PHOSITA's level of skill); *In re* Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness." (quoted in KSR Int'l v. Teleflex Inc., 550 U.S. 398, 418 (2007)).

145. For examples of courts chastising the Patent Office for subjective judgments, see *In re* Newman, 782 F.2d 971, 974 (Fed. Cir. 1986) (explaining that the Patent Office should not attempt to ascertain the scientific explanations because the agency "is not a guarantor of scientific theory"), and *In re* Ratti, 270 F.2d 810, 814 (C.C.P.A. 1959) (rejecting the Patent Office's contention that an invention must possess "some definite advantage over the prior art" in order to be patentable) (emphasis omitted)).

146. *See* Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA?*

nonobviousness—the patentability requirements involving highly fact-intensive inquiries—it is probably a bit of both.[147] To see how, consider the helpful discussion that Professors Robert Merges and Richard Nelson provide in the case of enablement:

> If the patent examiner can point to something in the prior art that indicates that some embodiments of the claimed invention will be impossible to make without more information than the inventor has disclosed, then the application may be rejected. But if the examiner cannot point to such an indication in the prior art, [P]atent [O]ffice policy dictates that even very broad claims may be allowed. This means that claims . . . often are allowed to cover ground that examiners *believe*, but cannot prove, is well beyond the area actually explored and disclosed by the inventor. The rule puts the burden of *disproving* enablement on the examiner. The rationale is that any other rule would leave claim scope too much in the hands of individual examiners and their technological forecasting abilities.[148]

If claim scope is to be narrowed, that task "is left to the *courts* in particular infringement suits."[149]

II. NEGATIVE EXTERNALITIES

A. ON PATENT REFORM

As noted earlier, certain practices and procedures at the Patent Office have contributed to the issuance of low-quality patents.[150] The agency's leadership recognizes the problem[151]

What the Patent System Can Learn from Administrative Law, 95 GEO. L.J. 269, 299 (2007) ("[T]he Federal Circuit has repeatedly stated that it grants no deference whatsoever to PTO legal interpretations."); Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1449–50 (1995) (raising the issue of technical competence and noting concerns from the members of the patent bar "who believe that the PTO could be more efficient and technologically savvy"); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1068–69 (2003) (arguing that the Federal Circuit should be more willing to defer to the Patent Office's technical expertise).

147. *See supra* notes 125–27 and accompanying text. It is important to note that enablement and nonobviousness as legal questions are reviewed de novo by the court. *See In re* '318 Patent Infringement Litig., 583 F.3d 1317, 1323 (Fed. Cir. 2009) (enablement); *In re* Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009) (nonobviousness).

148. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848–49 (1990) (internal citations omitted).

149. *Id.* at 849 (emphasis added); *cf. supra* notes 102–05 and accompanying text (exploring the view that the Patent Office's examination is just an initial determination of issues that must be resolved by the courts).

150. *See supra* notes 11–18 and accompanying text.

151. *See, e.g.*, Request for Comments on Enhancement in the Quality of Patents, 74 Fed. Reg. 65,093, 65,093–100 (Dec. 9, 2009); David Kappos, *Talk-*

and has taken steps to provide the examining corps with the time, tools, and incentives necessary to help ensure a more robust examination of patent applications.[152] It is hoped that these measures will reduce the number of questionable patents that issue.[153]

But the presumption of patentability and current allocations of burdens of proof pose major obstacles to achieving this goal. Even if examiners are better equipped and more incentivized to do their job, compelling them to affirmatively prove unpatentability still gives applicants the upper hand in the process. As explained in the Federal Trade Commission's 2003 report on the patent system and legislative and administrative changes that could improve it:

> The *ex parte* nature of the [examination] proceeding leaves the examiner on his or her own to evaluate and challenge applicants' assertions. Because the courts have placed the burden on the PTO to demonstrate grounds for rejecting a patent, rather than on the applicant to demonstrate that it meets the statutory criteria, difficulties in assembling responsive evidence work in favor of patent applicants.[154]

This predilection toward patent issuance counteracts efforts to both improve patent examination quality and to reduce overall application volume (and hence, the application backlog)[155] by deterring filings for frivolous inventions.[156]

B. ON INNOVATION AND PATENT POLICY

The patent system's overarching goal is to promote scientific and technological progress.[157] In theory, each of the indi-

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ing Quality, DIRECTOR'S FORUM: DAVID KAPPOS' PUB. BLOG (Sept. 3, 2010, 9:19 AM), http://www.uspto.gov/blog/director/entry/talking_quality.

152. *See* sources cited *supra* note 27.

153. *See* sources cited *supra* notes 27, 151.

154. FTC REPORT, *supra* note 8, ch. 5, at 8; *see also id.* Executive Summary, at 8 ("A plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application is filed.").

155. *See supra* note 17.

156. *See supra* note 26 and accompanying text (discussing how a robust examination regime can discourage frivolous filings, whereas a lax regime has the opposite effect).

157. This goal emanates from the Intellectual Property Clause of the Constitution: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8; *see also* Bilski v. Kappos, 130 S. Ct. 3218, 3236 (2010) (Stevens, J., concurring) (explaining that Intellectual Property Clause empowered Congress to pass "a series of patent laws . . . as a means of encouraging innovation"); Eldred v. Ashcroft, 537 U.S. 186, 223–24 (2003) (noting that the constitutional command for "limited times" is the "ultimate purpose" of the patent system); Motion Picture Patents

vidual statutory requirements for patentability seeks to further this objective.[158] But given that the presumption of patentability presupposes that every patent application fully complies with each requirement,[159] an important question is whether the presumption of patentability can interfere with the functioning of the statutory requirements and actually *impede* scientific and technological progress.

It seems that the negative impact of the presumption has a greater adverse effect on some statutory requirements than on others. For instance, certain judicially created rules and standards pertaining to the law of novelty[160] and nonobviousness[161]

Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) ("[T]he primary purpose of our patent laws . . . is 'to promote the progress of science and useful arts.'" (citations omitted)); EDWARD WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE 125–26 (2002) (explaining that in the latter part of the eighteenth century, the term "science" was synonymous with "knowledge" and "learning"); Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50, 54 (1949) (noting that the term "useful arts" is synonymous with the word "technology").

158. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 148 (1989) (noting that an invention which lacks novelty not only adds nothing to the sum of human knowledge, but "would in fact injure the public by removing existing knowledge from public use"); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed. Cir. 1999) (noting that the purpose of the enablement requirement is to ensure enrichment of public knowledge); Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("The utility requirement has its origin in article I, section 8 of the Constitution, which indicates that the purpose of empowering Congress to authorize the granting of patents is 'to promote progress of . . . *useful* arts.'").

159. *See supra* note 46 and accompanying text.

160. Novelty ensures that an invention is new by denying a patent if the claimed subject matter is identical to what is already known. *See* 35 U.S.C. §§ 101–102 (2006); *In re* Marshall, 578 F.2d 301, 304 (C.C.P.A. 1978) (citations omitted). An invention enjoys a presumption of novelty, which means that the examiner must prove that the invention already exists in the prior art. *In re* Wilder, 429 F.2d 447, 450 (C.C.P.A. 1970) (quoting § 102, which states that "a person shall be entitled to a patent unless [one of the statutory exclusions is shown]"); *see also supra* Part I.A. To illustrate how the novelty doctrine can temper the presumption, suppose that the invention at issue is a device, and the examiner finds a prior art reference which discloses a picture of an identical device but does not explain how to make it. The courts have held that the examiner is allowed to presume that a PHOSITA could have made the device disclosed in the prior art. *In re* Antor Media Corp., 689 F.3d 1282, 1287–88 (Fed. Cir. 2012); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 & n.21 (Fed. Cir. 2003) (explaining this presumption and its roots in policy). To move forward, the burden shifts to the *applicant* to prove that a PHOSITA could not have made the device without undue experimentation. *Id.* (citing *In re* Sasse, 629 F.2d 675, 681 (C.C.P.A. 1980)). If the applicant cannot do this, the device is unpatentable for a lack of novelty. *See*

can temper the presumption in certain situations by placing a heavier burden on the applicant.[162] Denying a patent in these situations fulfills a basic policy objective of the patent system: to not allow a patent to issue which would impinge upon the public's right to unfettered access to technology already in the public domain.[163]

Wilder, 429 F.2d at 450–52 (outlining the burden-shifting process); *In re* Jacobs, 318 F.2d 743, 745 (C.C.P.A. 1963) (stating that an applicant must carry the burden of proof to prevail).

161. Nonobviousness ensures that an invention is "new enough." 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.01, at 3–9 (2012); *see also* Joseph Scott Miller, *Nonobviousness: Looking Back and Looking Ahead*, *in* 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 2 (Peter K. Yu ed., 2007) ("[N]onobviousness divides the patentably new from the unpatentably new."). The law denies patents for trivial extensions of technology already in the public domain. 35 U.S.C. § 103(a) (2006); *see* sources cited *supra* note 127. Nonobviousness does not target inventions that are identically disclosed in the prior art, but rather those that are sufficiently close to the prior art and within the PHOSITA's technical grasp at the time the claimed invention is made. 35 U.S.C. § 103(a); *see* CRAIG ALLEN NARD, THE LAW OF PATENTS 305 (2d ed. 2011). An examiner must evaluate nonobviousness by considering the scope and content of the relevant prior art; the differences between the prior art and the claimed invention, the PHOSITA's level of skill, and secondary considerations which provide objective proof of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966). The scope and flexible nature of the nonobviousness standard "has traditionally represented the principal substantive hurdle for patentability." Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 19 (2004). *See generally* NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980) (providing a compilation of words addressing the nonobviousness standard). Importantly for present purposes, the barrier is now much higher than before, following a recent Supreme Court decision which makes it easier to reject patent applications for a lack of nonobviousness. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007) (rejecting the Federal Circuit's rigid test for nonobviousness due to its inconsistency with the "expansive and flexible" approach set forth in Supreme Court precedent). After *KSR*, the Director of the PTO even stated that "some claims that may have been found to be non-obvious before *KSR* will now correctly be found to be obvious." David A. Kappos, *The Impact of KSR*, DIRS. FORUM: DAVID A. KAPPOS' PUB. BLOG (Nov. 24, 2009, 1:58 PM), http://www.uspto.gov/blog/director/entry/the_impact_of_ksr.

162. *See, e.g.*, *Antor Media*, 689 F.3d at 1287–88; *see also* discussion *supra* note 160.

163. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 65 (1998); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("[T]he stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the use of the public."); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) ("[N]o patent should be granted which withdraws from the public domain technology already available to the public." (citing *Graham*, 383 U.S. at 6)).

However, the situation is quite different for enablement—the patentability requirement which "lies at the heart of the patent bargain . . . ."[164] By requiring an applicant to provide a disclosure sufficient to teach a PHOSITA how to make and use the full scope of the invention without undue experimentation,[165] enablement ensures that the applicant's disclosure sufficiently enriches public knowledge in exchange for the government-granted right to exclude.[166] There is hope that the knowledge gained will reduce R&D waste,[167] spur creativity,[168] and ultimately extend the frontiers of science and technology.[169]

Importantly, and in contrast to novelty and nonobviousness, the presumption of patentability is *not* tempered in the enablement context because the substantive law of enablement has a strong pro-patent bias.[170] This becomes clear when one looks at the burden faced by an examiner who wants to mount an enablement challenge. The key factor in the enablement inquiry is the substantive teaching provided in the ap-

164. 3 CHISUM, *supra* note 161, § 7.01, at 7–9; *see* LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (describing enablement as the essential aspect of the patent bargain).

165. *See supra* notes 70, 72 (describing the "without undue experimentation" requirement for enablement).

166. *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed. Cir. 1999); *see also* Brenner v. Manson, 383 U.S. 519, 533 (1966) ("[O]ne of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions."); WALTERSCHEID, *supra* note 157, at 143 (explaining that an essential purpose of the patent system under the quid pro quo (or "exchange-for-secrets") rationale is to assure the dissemination to the public of technical information it would not otherwise get); FTC REPORT, *supra* note 8, ch. 4, at 3–4 (explaining that enablement plays a central role in "safeguard[ing] the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others . . . can learn").

167. *See* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 n.79 (1994).

168. *See* MICHAEL A. GOLLIN, DRIVING INNOVATION 15–19 (2008) (explaining that disclosure adds to the pool of accessible knowledge which other creative individuals can use and improve upon); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 548–49 (2009) ("[D]isclosure can stimulate others to design around the invention or conceive of new inventions—either by improving upon the invention or by being inspired by it—even during the patent term." (citations omitted)); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 132–33 (2006) (making a similar argument).

169. *See* ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW § 1.2, at 6 (2004) (noting that patents enrich the public domain and thus support further innovation).

170. Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 143–54 (2008).

plicant's disclosure.[171] Gauging the sufficiency of this teaching is easiest when the examiner can evaluate actual experimental data or the details of one or more working embodiments of the invention.[172] But unlike the rules of mainstream science, which "require actual performance of every experimental detail"[173] as a prerequisite for publication, in patent law an applicant can obtain a patent with no (or very little) actual proof of concept or pre-filing experimentation.[174] In fact, patent law "explicitly assumes the need for more experimentation after filing to actually implement the invention."[175] Nevertheless, examiners must afford every application a presumption of enablement even if there is minimal teaching disclosed therein.[176]

While this presumption might not be a cause for concern for simple inventions like paper clips and broom rakes,[177] it raises questions for more complex inventions like chemical compounds or sophisticated devices.[178] These inventions often

171. *See* Sitrick v. DreamWorks, LLC, 516 F.3d 993, 1000 (Fed. Cir. 2008) (noting that an enablement analysis begins with the disclosure).

172. *Cf.* Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 652–53 (2010) [hereinafter Seymore, *Teaching Function*] (advocating for a working example requirement for complex technologies which would, among other things, simplify the enablement analysis).

173. Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1377 (Fed. Cir. 2003) (Newman, J., dissenting).

174. *See, e.g.*, Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." (quoting *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956))). It is well settled in U.S. patent law that the concept itself—and not any physical act—is the key facet of the inventive process. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60–61 (1998) ("[T]he word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea.").

175. Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 93 (2009) [hereinafter Cotropia, *Early Filing*] (citing Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314–15 (Fed. Cir. 2008)).

176. *See In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining that the Patent Office must accept the applicant's disclosure "as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support"); *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("[A]pplicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112." (citing *Marzocchi*, 439 F.2d at 224)).

177. *See* Seymore, *Teaching Function*, *supra* note 172, at 644 (arguing that a PHOSITA can make simple inventions with a minimal amount of teaching from the inventor).

178. *See id.*

require detailed teaching and guidance for the PHOSITA to make and use.[179] The absence of working examples, combined with the aforementioned information deficit,[180] make it hard for examiners to adequately gauge enablement.[181] It is also likely that a PHOSITA will need to engage in undue experimentation to practice the full scope of the invention.[182]

Though it is true that the Federal Circuit has started to police compliance with enablement more aggressively in recent years,[183] the fact still remains that an examiner who questions enablement still bears the burdens of both building a prima facie case of nonenablement and carrying the ultimate burden of

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179. *See id.* at 644–45 (arguing that PHOSITAs in complex fields must often engage in trial and error to figure out what works; in fields like chemistry, there is a danger that embodiments not actually reduced to practice cannot be made); *see also* Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (determining that a disclosure which enabled an injector with a pressure jacket was insufficient to support a claim that covered injectors both with and without a pressure jacket); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (explaining that a written description which only described a single embodiment of the invention, using aluminum with a certain percentage of silicon, failed to enable claims covering embodiments with other percentages of silicon).

180. *See* discussion *supra* Part I.C.1.

181. *See, e.g.*, Beckman Instruments, Inc. v. Chemtronics, Inc., 439 F.2d 1369, 1378–79 (5th Cir. 1970) (noting that in the absence of its own testing facilities, the Patent Office must rely on information presented to it); FTC REPORT, *supra* note 8, ch. 5, at 9 ("Yet the PTO lacks testing facilities, and assertions that cannot be overcome by documentary evidence promptly identifiable by the examiner often must be accepted."). A Patent Office official has explained the problem:

> [T]o a large degree when the going gets tough, certainly the applicant is in the position to have the experts to do the testing, to submit documentary evidence to show why the examiner should allow the case. And, of course[,] we don't have laboratories, and we don't have independent experts in that regard. So therefore, we are really compelled to accept some of that, particularly from the standpoint of the fact finding, that is presented to us.

Id. (alteration in original) (quoting Stephen G. Kunin, former Deputy Commissioner for Patent Examination Policy at the Patent Office).

182. In certain complex fields, "the technical scope and substance of the disclosure are very important because the PHOSITA must rely heavily, if not exclusively, on the instruction provided within the four corners of the patent document in order to practice the invention." Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1528 (2011); *see also* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) (making a similar observation); *In re* Strahilevitz, 668 F.2d 1229, 1232 (C.C.P.A. 1982) (explaining that working examples are desirable in complex technologies).

183. *See, e.g.*, ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010); cases cited *supra* note 179.

persuasion on the issue.[184] These burdens tip the scales toward patent issuance not only because of the examiner's time pressures and incentives discussed above,[185] but also because "[i]t is actually very difficult to offer rigorous proof that something cannot be done . . . ."[186] Thus, it is easy to see how dubiously enabled patents (and thus, patents of dubious quality) can slip through the cracks.

While all would agree that the issuance of nonenabled patents is far from ideal, there is less consensus as to whether or how to address the problem. For instance, it has been argued that suboptimal enablement is not surprising—and perhaps justifiable—given that "the patent law[s] place[] strong pressure on filing the patent application *early* in the development of the technology, often before . . . all of the boundaries [are] fully explored."[187]

Commentators point out that inventors must often file before actually reducing the invention to practice in order to attract investors,[188] minimize risk,[189] and to safeguard patent rights in the United States and abroad.[190]

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184. *See* discussion *supra* Part I.A.

185. *See supra* notes 11–18 and accompanying text.

186. Arthur Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763, 764 (1967); *see also* Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part I)*, 62 J. PAT. OFF. SOC'Y 217, 219–20 (1980) (explaining that obtaining proof can be a major problem for examiners, particularly since they must provide reasons and evidence to establish a prima facie case of unpatentability).

187. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (en banc) (Newman, J., concurring) (emphasis added), *rev'd on other grounds*, 520 U.S. 17 (1997); *see also* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267–71 (1977) [hereinafter Kitch, *Nature and Function*] (explaining the rules in patent law that force and permit early filing).

188. It is axiomatic in patent law that many inventors must rely on investors to cover the hefty costs of patent procurement and commercialization. *See* JOHN SAMSON, INVENTIONS AND THEIR COMMERCIAL DEVELOPMENT 51 (1896) ("To have the use of capital is nearly always indispensable for the development of an invention, and, unless the inventor is of that fortunate class who have the means to work their own patents, he must appeal for support to one or more people with money."); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 143–44 (2000) (discussing the need for venture capital); Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 759 (1999) ("The prospect of certainty in the patentee's property interest has several benefits, one of which is to create a sense of security which permits the patentee to secure risk capital from investors, which in turn facilitates the commercialization of the claimed invention." (citing Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985) ("[E]ncouragement of investment-based risk is the fundamen-

But this problem warrants more attention because allowing dubiously enabled patents to issue can impede scientific and technological progress. For example, the current regime encourages inventors to file patents on underdeveloped inventions, or worse, on mere ideas.[191] Such patents often provide dubious guidance to the PHOSITA, add little or nothing to the public storehouse of technical knowledge,[192] and supply little technical fodder for follow-on researchers to build upon.[193] In addition, these patents can create insurmountable roadblocks (intentionally or not)[194] for others with meritorious inventions.[195]

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tal purpose of the patent grant . . . .")).

189. *See, e.g.*, Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 393–94 (2010) ("If building a prototype is costly—take, for example, fabricating a new type of computer chip—the risks of not securing a patent [before actual reduction to practice] may be too large to justify doing so.").

190. *See* 35 U.S.C. § 102(b) (2006) (encouraging diligence by penalizing inventors for delay in filing patent applications); Convention on the Grant of European Patents, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272 (invoking an absolute novelty requirement which regards any pre-filing disclosure, including activity by the inventor, as patent defeating).

191. *Cf.* Christopher A. Harkins, *Fending Off Paper Patents and Patent Trolls: A Novel "Cold Fusion" Defense Because Changing Times Demand It*, 17 ALB. L.J. SCI. & TECH. 407, 453 (2007) (explaining that the lack of a requirement for an inventor "[to] actually have a complete and operative invention . . . [at the time of filing increases the] potential that the [claims] will protect speculative ideas . . . . With just a little time, money, and imagination, one may [obtain a patent] . . . without inventing anything . . . .").

192. *See infra* note 305 and accompanying text.

193. In other words, the disclosure probably lacks sufficient technical detail to be helpful. Thus, it does little to advance technological progress, which is commanded by the Constitution. *See* Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

194. For instance, so-called "nuisance" prior art describing an unworkable invention "can . . . be generated as a result of a bona fide attempt at a constructive reduction to practice that for some unexpected reason fails to work as disclosed." David S. Wainwright, *Patenting Around Nuisance Prior Art*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 221, 223–24 (1999). Innocuously disclosed information which has the same effect is often described as "technical junk." *Id.* at 222, 223 n.3.

195. A good example is when an early filer strategically drafts claims which cover undeveloped technology. *See* BESSEN & MEURER, *supra* note 19, at 67 (arguing that the practice "penalizes real innovators who operate in the shadow of early, broad claims"); Wainwright, *supra* note 194, at 221–22 (explaining how nuisance prior art can discourage applicants to the point of abandoning their patent applications); *see also* Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1975 (2005) (exploring the practice and discussing how patent prosecutors draft claims to "mitigate problems with language and later-developed technology").

III. TOWARD A PRESUMPTION OF UNPATENTABILITY

This Article has shown that various presumptions and procedural aspects of patent examination tip the scales in favor of issuance once a patent application is filed. And since applicants are presumptively entitled to receive a patent, anyone who files a patent on anything is "in a really great position" from the outset.[196] From an evidentiary standpoint, the biggest problem facing an examiner who seeks to challenge patentability is the dual burden of building a prima facie case of patentability and carrying the ultimate burden of persuasion on the issue by a preponderance of the evidence.[197] According to current case law, the Patent Office *must* issue a patent if the examiner fails to do both.[198] To address this problem and rebalance the scales of patentability, this Part offers a new evidentiary framework for patent examination.

A. RESTRUCTURING THE PROOF PARADIGM

1. How It Would Work

The starting point for the proposal is that rebalancing the scales of patentability—and thus making the issuance of a patent far from a sure thing—will require three key changes in the rules of patent examination. First, the locution of the dual burdens would be decoupled such that the initial burden of coming forward with evidence of unpatentability (building a prima facie case) would remain with the examiner but the burden of persuasion on the ultimate issue would now rest with the applicant. Second, the current presumption of patentability would be replaced with a presumption of *un*patentability. As a result, an applicant who could not adduce proof of patentability by a preponderance of the evidence would face a rejection. Third, in an effort to produce more technically robust patents, the restrictions on amending patent documents after filing would be relaxed so that an applicant who adduces proof of patentability could incorporate the additional information into the issued patent.

196. FTC REPORT, *supra* note 8, ch. 5, at 9 n.61 ("[P]atent applicants are in a really great position because by filing an application they're presumptively entitled to receive the grant." (quoting Professor John R. Thomas)).

197. *See supra* Part I.A.

198. *See supra* note 45.

2. Illustrations

Adopting this framework would recalibrate the entire patent procurement process by making it less pro-applicant. Yet, given the differences between the various statutory standards of patentability, it stands to reason that the proposed regime would have a greater impact in certain factual scenarios. Two scenarios are explored below.

a. Close Cases

The first scenario is when the examiner and the applicant are at or near equipoise over patentability.[199] To illustrate, suppose that in 2007 an inventor develops a stainless steel dinner fork with five tines. Believing that the invention does a better job of spearing food and holding it in place than the traditional forks (with fewer tines), the inventor files a patent application later that year claiming the fork. Though multi-tined forks exist in the prior art, the claimed device is novel because it is not identically disclosed therein.[200]

Turning to nonobviousness, the examiner finds two prior art references from the same field of endeavor[201] which teach all of the limitations[202] of the claimed device: a cutlery book published in 1985 disclosing a four-tined stainless steel dinner fork and a merchandise catalog from 1939 disclosing a silver five-tined *serving* fork. After making the factual findings set forth by the Supreme Court in *Graham v. John Deere Co.*[203] as to the scope and content of the prior art, the differences between the prior art and the claimed invention, and the PHOSITA's level of skill,[204] the examiner concludes that it would have been obvi-

199. In other words, having considered all of the evidence, the examiner concludes that it is equally likely that the invention is patentable or unpatentable. *See* Fleming James, Jr., *Burdens of Proof*, 47 VA. L. REV. 51, 51–52 (1961) (discussing equipoise).

200. For a discussion of the novelty requirement, see *supra* note 160.

201. Nonobviousness is discussed *supra* note 161. Briefly, a reference qualifies as § 103(a) prior art if it is analogous to the field of invention. *In re* Kahn, 441 F.3d 977, 986–87 (Fed. Cir. 2006) (citing Graham v. John Deere Co., 383 U.S. 1, 35 (1966)). References drawn from the same field of endeavor are considered analogous. *Id.* at 987.

202. A patent claim must define "the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 para. 2 (2006). A claim element further limits the breadth of the claim. 1 CHISUM, *supra* note 161, at Gl-3. In this illustration, "stainless steel," "dinner," and "five-tine[d]" are claim limitations.

203. 383 U.S. at 17.

204. *Id.*; *see also* discussion *supra* note 127.

ous for a PHOSITA at the time of the invention to produce the claimed device.

The examiner supports this conclusion with two rationales. First, the examiner contends that a PHOSITA could have combined the teachings of the two references in a predictable manner[205] to produce the claimed device with a reasonable expectation of success.[206] Second, the examiner contends that the claimed invention was obvious to try because a PHOSITA seeking to solve the problem articulated by the inventor would have been aware of a finite number of predictable solutions (adding tines) and thus would have had good reason to pursue and a reasonable expectation of successfully arriving at the claimed invention.[207]

Having made a prima facie case of obviousness,[208] the burden of going forward shifts to the applicant.[209] The applicant attempts to rebut the prima facie case by arguing that the claimed device satisfies a long-felt but unresolved need in the art.[210] The examiner responds with a request for actual proof,[211] specifically, "objective evidence that an art recognized problem existed in the art for a long period of time without solution."[212] Reminded that "the mere passage of time without the claimed

205. *See* MPEP, *supra* note 56, § 2143(A) (noting that combining references according to known methods to produce a predictable result is an appropriate rationale to support a conclusion of obviousness); *cf.* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007) (explaining that a combination of elements "must do more than yield a predictable result").

206. *See In re* O'Farrell, 853 F.2d 894, 903–04 (Fed. Cir. 1988) ("Obviousness does not require absolute predictability . . . . [A]ll that is required is a reasonable expectation of success."); *see also* PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360–64 (Fed. Cir. 2007) (reaffirming "reasonable expectation of success" jurisprudence post-*KSR*).

207. *See KSR*, 550 U.S. at 421 (endorsing the "obvious to try" rationale); MPEP, *supra* note 56, § 2143(A) (same).

208. *See In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (interpreting *Graham v. John Deere* to require the Patent Office to provide a factual basis for a § 103 rejection as a part of the prima facie case).

209. *Id.*

210. *See supra* note 127.

211. During the course of patent examination, the examiner may request "[t]echnical information known to [the] applicant concerning . . . the disclosure, the claimed subject matter, other factual information pertinent to patentability, or concerning the accuracy of the examiner's stated interpretation of such items." 37 C.F.R. § 1.105 (a)(1)(viii) (2012).

212. MPEP, *supra* note 56, § 716.04. In addition, "significant improvements in the art that bear on the inventor's solution dilute the significance of prior need and failure." 2 CHISUM, *supra* note 161, § 5.05[1]b.

invention is not evidence of nonobviousness,"[213] the applicant abandons this strategy and attempts to prove nonobviousness by showing praise for the invention by others in the art.[214] The proffered evidence includes a copy of a short write-up about the invention in a cutlery trade publication and positive commentary about it in *Better Homes and Gardens* magazine.

Upon consideration of the entire record,[215] the examiner finds that the nonobviousness issue is in equipoise. Under the current regime, equipoise means that "the applicant is entitled to the patent"[216] absent any other grounds for unpatentability because "the applicant does not bear the ultimate burden of persuasion on the issue."[217] The proposed paradigm, on the other hand, would produce the opposite result thereby leaving the new fork unpatentable.

Denying patentability in this context makes sense from a technical standpoint and aligns with core goals of the patent system. Applying the proposed paradigm allows the nonobviousness requirement to truly fulfill its statutory purpose: to prevent the issuance of patents for trivial extensions of what is already in the public domain.[218] It does so by targeting

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213. *In re* Kahn, 441 F.3d 977, 991–92 (Fed. Cir. 2006) (quoting Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004)).

214. The Federal Circuit has recognized praise as a secondary (objective) indicator of nonobviousness. Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120, 1129 (Fed. Cir. 2000) (citing Allen Archery, Inc. v. Browning Mfg. Co., 819 F.2d 1087, 1092 (Fed. Cir. 1987) (considering praise)); *see also* 2 CHISUM, *supra* note 161, § 5.05[4] (exploring the history of "reaction of experts in the field to the invention upon its initial public appearance" as objective evidence of nonobviousness).

215. *See supra* note 56 and accompanying text.

216. *In re* Oetiker, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (Plager, J., concurring).

217. *Id.*; *see also* Kevin M. Clermont, *Procedure's Magical Number Three: Psychological Bases for Standards of Decision*, 72 CORNELL L. REV. 1115, 1119 n.13 (1987) ("[T]he law handles a finding of equipoise by means of the burden of persuasion."); James, *supra* note 199, at 51–52 (noting that in equipoise, the party that bears the risk of nonpersuasion loses).

218. *See* discussion *supra* note 127. By constitutional command, a patent can neither remove such knowledge from the public domain nor limit free access to those materials already available. Graham v. John Deere Co., 383 U.S. 1, 6 (1966); *see also* Kitch, *Nature and Function*, *supra* note 187, at 283 (arguing that patents should not be granted for the use and development of known technical information because "proper incentives for its acquisition and use exist without a property right"). Rather, a patent can only be awarded for technical advances which add to the storehouse of useful knowledge. *Graham*, 383 U.S. at 6 ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.'"); *cf.* Great

inventions that are sufficiently close to the prior art and within the PHOSITA's technical grasp at the time the claimed invention is made.[219] Thus, nonobviousness "creates a 'patent-free' zone around the state of the art,"[220] allowing the PHOSITA to substitute materials, streamline processes, and "[to make] the usual marginal improvements which occur as a technology matures."[221]

The nonobviousness requirement seeks to "weed[] out those inventions which would not be disclosed or devised but for the inducement of a patent."[222] Here, modifying known devices (a four-tined stainless steel dinner fork and a five-tined serving fork) to produce a predictable, trivial modification (a stainless-steel five-tined dinner fork) draws on knowledge already in the public domain and well within the PHOSITA's skill and ordinary creativity.[223] Thus, (the inducement of) a patent is unnec-

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Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152 (1950) ("The conjunction or concert of known elements must contribute something; only when the whole in some way exceeds the sum of its parts is the accumulation of old devices patentable."). As the Supreme Court recently explained:

> We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007); *cf.* Edmund W. Kitch, Graham v. John Deere Co.*: New Standards for Patents*, 1966 SUP. CT. REV. 293, 301 (explaining that nonobviousness is based on the principle that "a patent should not be granted for an innovation unless [it] would have been unlikely to have been developed absent the prospect of a patent").

219. *See* 35 U.S.C. § 103(a) (2006); NARD, *supra* note 161, at 305 (discussing the nonobviousness requirement); *cf. In re* Fisher, 421 F.3d 1365, 1382 (Fed. Cir. 2005) (Rader, J., dissenting) ("The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103.").

220. MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 288 (3d ed. 2009).

221. *Id.*

222. *Graham*, 383 U.S. at 11.

223. *See* Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 60–62 (1969) (explaining that an invention derived from old elements which does no more than expected is obvious, despite being new and useful); *cf. KSR*, 550 U.S. at 421, 427 (noting that the claimed design step was "well within the grasp" of a PHOSITA—a person of "ordinary skill in the relevant art"). Joseph Scott Miller elaborates:

essary since the fork came about through ordinary technological progress.[224]

b. Challenging the Sufficiency of Disclosure

The second scenario is when the sufficiency of the applicant's disclosure—and enablement in particular—is at issue. To illustrate, consider another hypothetical example. Suppose an inventor at a drug company seeks to patent a new class of pharmaceutical compounds. The patent application includes a generic claim that, by claiming a core chemical structure with an array of twenty variables appended to it, encompasses billions of compounds.[225] As is typical in pharmaceutical cases, the claim is incredibly broad[226]—here because it is possible to substitute each of the twenty variables appended to the core struc-

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> When a [PHOSITA] encounters a new problem, he or she will create a new ordinary invention—an obvious invention—as a matter of course. We do not need to provide a reward to draw into existence the obvious inventions that fall within the [PHOSITA's] skill. The need to solve practical problems is sufficient to spark [their development], and their suitability for the needs they satisfy is itself a sufficient reward.

Miller, *supra* note 161, at 2.

224. *See supra* note 218 and text accompanying note 220; Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547, 549 (2008) ("The nonobviousness threshold may be used as a 'stick' to induce researchers to pursue more difficult, socially preferred research projects."); Miller, *supra* note 161, at 2 ("It is socially wasteful for us to pay a patent-backed premium for an innovation that we are almost certain to receive for free and just as early.").

225. *See In re* Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (explaining that the practice of describing a class of chemical compounds in terms of structural formulas, where the substituents are recited in the claim language, has been sanctioned by the courts). This style of claiming—ubiquitous in the chemical and pharmaceutical arts—is called Markush practice. *See In re* Harnisch, 631 F.2d 716, 719–20 (C.C.P.A. 1980) (explaining the history and current law of Markush practice). For an example of this style of claiming, see U.S. Patent No. 4,801,613 (filed June 17, 1987). Claim 1 of the '613 patent refers to "[a] modified bradykinin type peptide having the formula A-Arg-B-C-D-W-X-Y-Z-Arg," where the variables A, B, C, D, W, X, Y, Z are each generic substructures reciting smaller peptides or amino acids. Thus, the primary generic structure contains eight smaller generic substructures. *See id.* cols. 19–20, ll. 1–41. All together, this claim covers 10,235,904 formulations of a peptide. For an extreme example, see U.S. Patent No. 5,422,351 (filed June 21, 1991) (including a structural formula in claim 1 which encompasses at least one novemdecillion (10^{60}, or one followed by sixty zeroes) compounds).

226. *See supra* text accompanying note 67 (discussing "broad" claims); *see also* Ned A. Israelson & Rose M Thiessen, *Chemical and Pharmaceutical Patents*, *in* DRAFTING PATENTS FOR LITIGATION AND LICENSING 455, 457 (Bradley C. Wright ed., 2008) (advising drafters of chemical patent applications to provide adequate support for claims that often covers billions of species).

ture with countless organic functional groups.[227] The patent application, however, only sets forth five compounds actually made. These five compounds are closely related to each other in that the same variable (one of the twenty) is substituted in each.

After construing the claims, assessing the PHOSITA's level of skill, and evaluating the teaching provided in the patent application,[228] the examiner determines that the disclosure only teaches a PHOSITA how to make a narrower subgenus of five-hundred compounds, not billions. As support for a prima facie case of nonenablement for the broad genus, the examiner recognizes that

> replacing a functional group on a chemical compound can often have highly unpredictable results. . . . [E]ven a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group . . . could result in either a significant improvement or reduction in the activity of the compound against a particular biological target.[229]

The point here is that a PHOSITA cannot extrapolate a result from a few embodiments across a broad genus with a reasonable expectation of success.[230]

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227. A functional group is a group of atoms within a molecule with specific chemical properties that represents a potential reaction site in a compound, and thus determines a molecule's chemical reactivity. *See generally* RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS (2d ed. 1999) (providing a comprehensive list of functional group preparations).

228. *See supra* notes 70–72 and accompanying text (discussing the factual inquiries underlying the enablement analysis).

229. Singh v. Brake, 317 F.3d 1334, 1344 (Fed. Cir. 2003) (citation omitted); *see also* Yasuko Kawai v. Metlesics, 480 F.2d 880, 891 (C.C.P.A. 1973) (explaining that with respect to the enablement of a method-of-treatment claim, a PHOSITA "is well aware that subtle changes in chemical compounds can radically alter the effects on a human body").

230. In fields like chemistry, results are often unpredictable because researchers often must engage in trial and error to figure out what works and what does not. Thus, a PHOSITA cannot predict if a reaction protocol which works for one compound will work for others. *See* Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997) (explaining that in the chemical arts, "a slight variation . . . can yield an unpredictable result or may not work at all"); *In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993) (testing enablement by determining if a skilled scientist would have believed reasonably that the inventor's success with the described embodiment(s) "could be extrapolated with a reasonable expectation of success" to other embodiments encompassed by the broad claims); *In re* Prutton, 200 F.2d 706, 712 (C.C.P.A. 1952) (holding that claims to a class of chemical compounds, which were sufficiently broad to involve some speculation, lack enablement, notwithstanding the presence of the operative specific examples within the class); Karen S. Canady, *The* Wright *Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 458 (1994).

Consequently, the examiner rejects the broad generic claim as prima facie nonenabled because a PHOSITA would have to engage in undue experimentation to practice its full scope.[231] At this point the burden shifts to the applicant to establish by a preponderance of the evidence that the PHOSITA's knowledge in combination with the applicant's teaching can actually enable the full scope of the generic claim. In response, the applicant argues that a well-trained organic chemist would know where to look in the scientific literature to fill in the technical gaps.[232] The examiner determines that the proffered evidence is insufficient to rebut the prima facie case because it is not a "persuasive argument[], supported by suitable [evidence] where necessary, that [a PHOSITA] would be able to make and use the claimed invention using the application as a guide."[233]

At this point, examination could take two paths. Consider first the scenario in which the applicant is unable or unwilling to produce the requisite evidence. Mindful of the presumption of unpatentability, the applicant voluntarily cancels the broad generic claim and pursues the narrower subgenus claim covering five-hundred compounds. The examiner allows that claim and the applicant ultimately obtains a *much narrower* patent—by eight orders of magnitude—than that which probably would have issued under the current regime.

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231. *See* Merges & Nelson, *supra* note 148, at 848 (explaining why such a rejection is proper). There is a danger that embodiments not described either cannot be made or may require experimentation which is unduly extensive. *See* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (explaining that "[e]nablement is lacking . . . because the undescribed embodiments cannot be made, based on the disclosure . . . without undue experimentation").

232. Applicants often point to the oft-cited statement that "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); *see also* Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) (explaining that the written description need not necessarily describe how to make and use every embodiment of the invention because the PHOSITA's "knowledge of the prior art and routine experimentation can often fill in the gaps" (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003))). However, "that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure." Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997), *cited with approval in* ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940–41 (Fed. Cir. 2010).

233. MPEP, *supra* note 56, § 2164.05; *see also In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (explaining that a "rejection for failure to teach . . . can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling").

Now consider a scenario in which the applicant adduces additional proof of patentability—most likely experimental details for more of the claimed compounds. As far as the burden is concerned, the additional technical information would provide more enablement and allow the applicant to obtain a patent with claims covering more than five-hundred compounds (but still narrower than what was originally sought).

In this latter scenario, the proposed regime would allow the applicant to amend the patent document to include this additional technical information. This would probably require the Federal Circuit and the Patent Office to liberalize the "new matter" doctrine which severely restricts the ability of applicants to amend patent documents.[234] The key question is whether the additional technical information "was inherently contained in the original application"[235]—a fact-based inquiry which depends on "the nature of the disclosure, the state of the art, and the nature of the added matter."[236] If the examiner makes a positive finding, the additional technical information would be incorporated into the issued patent. Thus, the resulting patent document would be more technically robust than the one originally filed.

B. NORMATIVE JUSTIFICATIONS

1. Retention of the Prima Facie Case

Recall that under the current regime, the examiner bears the burden of establishing a prima facie case of unpatentability.[237] Once established, the burden of production shifts to the applicant to rebut the inference of unpatentability

234. When an applicant amends the written description, the Patent Office instructs examiners to be on the alert for "new matter." *See* 35 U.S.C. § 132(a) (2006) ("No amendment shall introduce new matter into the disclosure of the invention."); 37 C.F.R. § 1.121 (2012); MPEP, *supra* note 56, § 706.03(o) (alerting examiners). "The written description requirement [of 35 U.S.C. § 112] and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001).

235. *TurboCare*, 264 F.3d at 1118 (quoting Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000)).

236. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1992).

237. *See* sources cited *supra* notes 45–49 and accompanying text. A prima facie case suffices as proof of a particular fact or issue "unless disproved or rebutted." BLACK'S LAW DICTIONARY 1310 (9th ed. 2009).

by a preponderance of the evidence.[238] If sufficient rebuttal evidence is produced, the inference "is dissipated"[239] and the examiner must consider *all* of the facts in evidence—including those adduced during later stages of prosecution—before drawing a final conclusion as to patentability.[240] On the other hand, insufficient rebuttal evidence compels a conclusion of unpatentability.[241]

The prima facie case is retained as a procedural device in the proposed framework for several reasons. First, in ex parte matters, it serves as an orderly mechanism for initially producing evidence,[242] and it "promotes the development of the written record"[243] of the proceedings before the Patent Office. The Federal Circuit has defended the prima facie case precisely because of this information-gathering function:

> [I]ts purpose is simply to provide sufficient notice to the applicant to facilitate his effective submission of information. Since the applicant is in the best position to cheaply provide information about the purported invention, the PTO's authority to shift the burden to obtain this information [after the prima facie case it met] is crucial to ensure that the PTO is not mak[ing] patentability determinations on insufficient facts and information.[244]

Second, without the prima facie case, an applicant would be hard-pressed to figure out why the invention is unpatentable. It would make little sense for the examiner "[to]

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238. *In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

239. *Piasecki*, 745 F.2d at 1472; *see also In re* Kumar, 418 F.3d 1361, 1366 (Fed. Cir. 2005) ("When rebuttal evidence is provided, the *prima facie* case dissolves, and the decision is made on the entirety of the evidence."); *Oetiker*, 977 F.2d at 1445 ("The term '*prima facie* case' refers only to the initial examination step."); *cf.* WIGMORE ON EVIDENCE, *supra* note 30, § 2491, at 305 (explaining that a presumption disappears when sufficient evidence is introduced to rebut it).

240. *See Oetiker*, 977 F.2d at 1445 ("[T]he ultimate determination of patentability is made on the entire record."); *Piasecki*, 745 F.2d at 1472 (noting that once the prima facie inference is rebutted, "the examiner must consider all of the evidence anew"); *In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976) (warning examiners not to become analytically fixated on the prima facie case or "to provide that decision with an undeservedly broadened umbrella effect").

241. *See* CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, FEDERAL EVIDENCE § 3:6 (3d ed. 2007) (describing the function of the presumptions).

242. *See Piasecki*, 745 F.2d at 1472; *see also In re* Dillon, 919 F.2d 688, 710 (Fed. Cir. 1990) ("[T]he principle underlying orderly patent examination is that the burden in the first instance is on the examiner to establish that the claimed invention is *prima facie* unpatentable . . . .").

243. *In re* Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

244. Hyatt v. Dudas, 492 F.3d 1365, 1370 (Fed. Cir. 2007) (internal quotations omitted).

sit mum, leaving the applicant to shoot arrows into the dark hoping to somehow hit a secret objection harbored by the examiner."[245] Finally, the prima facie case mitigates arbitrariness to the extent that it prevents the Patent Office from denying patents without a sufficient factual basis.[246]

2. Reallocation of the Burden of Persuasion

The principal significance of the burden of persuasion is to determine, upon consideration of all of the evidence, which party wins if the decisionmaker is in doubt.[247] Where the burden rests can depend upon the existence of a presumption since the latter can assign the former.[248] This is the case in patent law because assigning the burden to the Patent Office stems from the presumption of patentability.[249] Since the proposed frame-

245. *Oetiker*, 977 F.2d at 1449 (Plager, J., concurring).

246. As Judge Plager once explained:

> The "prima facie case" notion . . . seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the prima facie case) to patentability, and give the applicant fair opportunity to meet those objections with evidence and argument. To that extent the concept serves to level the playing field and reduces the likelihood of administrative arbitrariness.

Id. (citation omitted); *see also supra* Part I.C (arguing that the current presumption of patentability is justified in part by the fear of Patent Office arbitrariness).

247. 2 KENNETH S. BROUN ET AL., MCCORMICK ON EVIDENCE § 336, at 472 (6th ed. 2006) [hereinafter MCCORMICK ON EVIDENCE]; James, *supra* note 199, at 51–52 (noting that in equipoise, the party that bears the risk of nonpersuasion loses); Chris William Sanchirico, *A Primary-Activity Approach to Proof Burdens*, 37 J. LEGAL STUD. 273, 273–74 (2008) ("The party bearing the burden of persuasion loses if the totality of both parties' evidence leaves the fact finder in equipoise regarding who should prevail.").

248. *See* MCCORMICK ON EVIDENCE, *supra* note 247, § 343, at 500 ("A presumption shifts the burden of producing evidence and may assign the burden of persuasion as well."); Ronald J. Allen, *Presumptions in Civil Actions Reconsidered*, 66 IOWA L. REV. 843, 845 (1981) (noting that presumptions have been used to allocate the burden of persuasion); Kenneth S. Broun, *The Unfulfillable Promise of One Rule for All Presumptions*, 62 N.C. L. REV. 697, 701 (1984) (same). Presumptions themselves are often "created by courts and by legislatures to accomplish various objectives or policies." Mason Ladd, *Presumptions in Civil Actions*, 1977 ARIZ. ST. L.J. 275, 279. Thus, creating a presumption which allocates the burden of persuasion allows the courts and legislatures to essentially choose the preferred result in close cases. *See* Paul H. Robinson, *Criminal Law Defenses: A Systematic Analysis*, 82 COLUM. L. REV. 199, 257 n.215 (1982).

249. *See, e.g.*, *In re* Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring); *Oetiker*, 977 F.2d at 1449; *In re* Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967).

work flips the presumption to one of unpatentability,[250] it logically reallocates the burden of persuasion to the applicant.

This reallocation is consistent with the scholarly literature on evidence. At first glance this might seem surprising because the burden of persuasion often rests with the same party that carries the initial burden of production.[251] Yet this is not a hard-and-fast rule. Evidence scholars have long urged that there is no single overarching principle which dictates how the burden of persuasion should be assigned.[252] Rather, it may depend upon a myriad of factors.[253] Two common factors—both of which are relevant for patent examination—are access to proof and substantive policy considerations.[254]

A doctrine has emerged which assigns the burden of persuasion to a party if it has superior information needed to prove an issue, even if that party does not bear the initial burden of producing evidence.[255] The Supreme Court recognizes and ap-

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250. *See supra* Part III.A.1.

251. *See* MCCORMICK ON EVIDENCE, *supra* note 247, § 337, at 477 (recognizing that the two burdens generally rest with the same party); MUELLER & KIRKPATRICK, *supra* note 241, § 3:3 (same); 21B CHARLES ALAN WRIGHT & KENNETH W. GRAHAM, JR., FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 5122, at 401 (2d ed. 2005) ("[T]he same party who has the burden of persuasion also starts out with the burden of producing evidence . . . .").

252. MCCORMICK ON EVIDENCE, *supra* note 247, § 337, at 477; *see also* James, *supra* note 199, at 62 ("[T]he production burden and the persuasion burden [do] not always march hand in hand." (citing JAMES BRADLEY THAYER, A PRELIMINARY TREATISE ON EVIDENCE AT THE COMMON LAW 370–78 (1898))).

253. *See, e.g.*, MCCORMICK ON EVIDENCE, *supra* note 247, § 337, at 477 (explaining that the allocation "will depend upon the weight that is given to any one or more of several factors, including: (1) the natural tendency to place the burdens on the party desiring change, (2) special policy considerations such as those disfavoring certain defenses, (3) convenience, (4) fairness, and (5) the judicial estimate of the probabilities"); MUELLER & KIRKPATRICK, *supra* note 241, § 3:3 (listing five factors: custom, substantive policy, access to proof, probable truth, and proof unavailable); WRIGHT & GRAHAM, *supra* note 251, § 5122, at 401–02 (discussing "disturb[ing] the status quo" and "[t]he Three Ps—Policy, Probability, and Possession of Proof"); Lakin v. Watkins Associated Indus., 863 P.2d 179, 189 (Cal. 1993) ("In determining whether the normal allocation of the burden of proof should be altered, the courts consider a number of factors: the knowledge of the parties concerning the particular fact, the availability of the evidence to the parties, the most desirable result in terms of public policy in the absence of proof of the particular fact, and the probability of the existence or nonexistence of the fact." (quoting CAL. EVID. CODE § 500 cmt. at 431 (West 1966)).

254. *See* sources cited *supra* note 253.

255. *See* JOHN MACARTHUR MAGUIRE, EVIDENCE: COMMON SENSE AND COMMON LAW 179 (1947) (asserting that the burden of persuasion "is to be borne by the party having peculiar knowledge of the facts"); MCCORMICK ON EVIDENCE, *supra* note 247, § 337, at 475 ("A doctrine often repeated by the

plies this doctrine because "considerations of fairness" require allocation to a party if the facts needed to establish an issue lie "peculiarly within [that party's] knowledge."[256] Several commentators have argued that this doctrine also makes sense from an economic perspective.[257]

In the patent examination context, it is the applicant who has superior information about the invention.[258] But applicants may be reluctant to share all of this information with the examiner. As Professor Timothy Holbrook has explained, "applicants do have incentives to withhold certain information and behave strategically, in part due to concerns over competition and in part due to concerns over the legal consequences their disclosures may create."[259] This is why the Patent Office must im-

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courts is that where the facts with regard to an issue lie peculiarly in the knowledge of a party, that party has the burden of proving the issue."); MUELLER & KIRKPATRICK, *supra* note 241, § 3:3 (discussing access to proof); Ronald J. Allen, *Presumptions, Inferences and Burden of Proof in Federal Civil Actions—An Anatomy of Unnecessary Ambiguity and a Proposal for Reform*, 76 NW. U. L. REV. 892, 899 (1982) (noting that the burden of persuasion is frequently allocated to the party on issues peculiarly within the knowledge of that party).

256. United States v. N.Y., New Haven & Hartford R.R. Co., 355 U.S. 253, 256 n.5 (1957) ("The ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary."); *see* Allseas Maritime, S.A. v. M/V Mimosa, 812 F.2d 243, 248 (5th Cir. 1987) (stating an exception to a party's burden of persuasion "when the facts with regard to an issue lie peculiarly in the knowledge of one party, and it would therefore be particularly onerous to require the other party to bear the burden of persuasion on the issue" (internal quotations omitted)); *see also* WIGMORE ON EVIDENCE, *supra* note 30, § 2486, at 291 (noting "peculiar means of knowledge" as a factor to consider in assigning the burden).

257. *See* Bruce L. Hay & Kathryn E. Spier, *Burdens of Proof in Civil Litigation: An Economic Perspective*, 26 J. LEGAL STUD. 413, 419 (1997) ("One party may have easier access to evidence than his opponent, meaning he can assemble the appropriate evidence at lower cost than his opponent. Other things being equal, the lower one party's relative costs, the stronger the argument for giving him the burden of proof."). A similar argument can be made for a party that has greater resources. *See* Richard A. Posner, *An Economic Approach to the Law of Evidence*, 51 STAN. L. REV. 1477, 1543 (1999) (arguing that burdens of production and persuasion are economizing devices and should therefore be assigned to the party with greatest access to resources).

258. *See supra* notes 132, 136, 181 and accompanying text.

259. Holbrook, *supra* note 138, at 818. With regard to competition, "patent applicants have the incentive to disclose 'just enough' to satisfy the patentability requirements of § 112 while retaining other aspects as trade secrets." *Id.* (citing R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PA. L. REV. 159, 214–16 (2002)). Regarding legal consequences, "the Federal Circuit's treatment of the patent document gives an

plement rules to compel disclosure in order to help minimize its information deficit.[260] In addition, commentators have argued that the Patent Office's limited resources hinder its ability to acquire all of the information that it needs to conduct robust examinations.[261] On the other hand, the applicant is often the "cheapest cost provider"[262] vis-à-vis the Patent Office when it comes to furnishing information for patent examination.[263] For these reasons, the superior information doctrine should be considered as a factor in reallocating the burden of persuasion to the applicant.

Another important factor for allocating the burden of persuasion is the policy goal of the underlying substantive law.[264] Some commentators suggest that this may be the most important factor.[265] Absent clear direction from Congress, the federal courts are not hesitant to allocate the burden in a manner consistent with their perceptions of good policy.[266] Importantly for present purposes, sometimes this policy choice is supported or reinforced with a presumption.[267] A good example comes from the common law of admiralty. In cases where a vessel hits a stationary object, a rebuttable presumption of fault arises and the burden of persuasion rests with the alliding vessel.[268] This rule furthers the policy goal of avoiding maritime accidents.[269]

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incentive for patent applicants to limit their disclosures to avoid potential estoppel-like consequences." *Id.*

260. *See supra* note 132 and accompanying text.

261. *See supra* note 28, *infra* notes 285, 295 and accompanying text.

262. Jason Rantanen & Lee Petherbridge, Commentary, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 29 (2011), http://www.michiganlawreview.org/assets/fi/110/rantanenpetherbridge.pdf.

263. *Id.* at 28 ("[W]here the cost of having the patent applicant provide information is relatively low, and particularly where the cost to the patent office of providing information is prohibitively high, the law allocates the cost of the information to the party seeking the exclusive rights.").

264. *See* WIGMORE ON EVIDENCE, *supra* note 30, § 2486, at 291 (explaining that allocating the burden of persuasion can be "merely a question of policy and fairness"); James, *supra* note 199, at 61 (noting that substantive policy considerations may be influential).

265. *See* MUELLER & KIRKPATRICK, *supra* note 241, § 3:3 ("First and perhaps most important, burdens are allocated to serve substantive policy . . . ."); *see also* WRIGHT & GRAHAM, *supra* note 251, § 5122, at 402 ("In determining the placement of burdens of proof, courts begin with the policy of the substantive law . . . .").

266. *See* Allen, *supra* note 255, at 898.

267. *See* WRIGHT & GRAHAM, *supra* note 251, § 5122, at 400.

268. *See* The Oregon, 158 U.S. 186, 192–93 (1895) (holding that a vessel moving under its own power that allides with a stationary object is presumed

The same rationale extends by analogy to the patent law context. As discussed in the next section, allocating the burden of persuasion to the applicant in combination with a presumption of unpatentability could be used to modulate applicant behavior and further certain policy objectives of the patent system.[270]

3. Allowing Post-Filing Amendments to Patent Documents

The proposal contemplates that inventors who are able to adduce proof of patentability will seek to incorporate the additional information into the patent document.[271] Allowing a post-filing amendment to the disclosure would yield an issued patent which would be more technically robust than what was originally filed. Nevertheless, one might ask if liberalizing the new matter doctrine would unfairly give an applicant a "second bite at the apple" with respect to compliance with § 112.[272] Possibly, but this prong of the proposal is designed to strike a balance between an inventor's need to file early[273] and a broader interest in using disclosure to promote the patent system's overarching goal of scientific and technological progress.[274] Finally, it is worth reiterating that allowing the post-filing amendments would still yield claims in the issued patent which would be narrower than those likely to issue under the current regime.[275]

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to be at fault and has the burden of persuasion to prove otherwise); The Louisiana, 70 U.S. (3 Wall.) 164, 173 (1865) (holding that a drifting vessel that allides with a stationary object is presumed to be at fault and has the burden of persuasion to prove otherwise). These drifting-vessel rules essentially apply the res ipsa loquitur doctrine to admiralty cases. *See* Rodi Yachts, Inc. v. Nat'l Marine, Inc., 984 F.2d 880, 886 (7th Cir. 1993) (citations omitted).

269. *See* Hood v. Knappton Corp., 986 F.2d 329, 331 (9th Cir. 1993) (discussing the policy goals of *The Louisiana* rule).

270. *See infra* Part III.C.

271. *See supra* Part III.A.1.

272. *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 977 (Fed. Cir. 2002) ("Every patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention."); *In re* Hogan, 559 F.2d 595, 604 (C.C.P.A. 1977) (explaining that compliance with enablement is gauged as of the applicant's effective filing date).

273. *See infra* Part III.C.2.

274. *See supra* Part II.B.

275. Enablement places an outer limit on the scope of the claims. *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). As discussed in the main text, under the current regime the

C. POLICY IMPLICATIONS

1. Patent (Examination) Quality

There is a general consensus that an important policy goal for patent law is to improve patent quality.[276] An overarching objective of quality improvement efforts is to reduce uncertainty throughout the patent system.[277] In theory, high patent quality would lead to less "uncertainty about the validity of granted patents, uncertainty about the scope of granted patents, uncertainty about whether a particular invention is patentable, and uncertainty about whether a valid patent will be fully enforced."[278]

Increased certainty would discourage opportunistic behavior such as rent-seeking patent acquisition and enforcement activities;[279] lower the overall amount, expense, and complexity of

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presumption of enablement tips the scales toward the issuance of a patent with broad claims. *See supra* notes 176–95 and accompanying text; *e.g.*, *supra* text accompanying notes 59–85 (providing a hypothetical example). Clearly the proposed presumption of unpatentability and reallocated burdens of proof would constrain claim scope, but exactly how much would depend on the nature and amount of proof adduced by the applicant. *See supra* Part III.A.2.b.

276. Jaffe, *supra* note 20, at 65.

277. For a description of some of the detrimental effects of uncertainty, see FTC REPORT, *supra* note 8, ch. 3, at 53–55 (explaining how low-quality patents create uncertainty and hinder innovation); Note, *Estopping the Madness at the PTO: Improving Patent Administration Through Prosecution History Estoppel*, 116 HARV. L. REV. 2164, 2165 (2003) ("[P]oor patent quality creates uncertainty over patent validity. This uncertainty increases transaction costs in licensing negotiations because parties must conduct duplicative research and prior art searches to determine if a particular patent is valid and worth licensing. Finally, by postponing the true validity determination until litigation, poor patent quality strains judicial resources."). Reducing uncertainty is a persistent concern in patent law. *See* Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938) (indicating that the primary purpose of notice is "to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights"); *see also* Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 813 (1988) (recognizing that one of Congress's goals in creating the Federal Circuit was to reduce uncertainty in the application of patent law); *In re* Zletz, 893 F.2d 319, 322 (Fed. Cir. 1989) ("An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

278. Wagner, *supra* note 3, at 2140.

279. *See* Thomas, *Patent Administration Reform*, *supra* note 10, at 731 (arguing that poor patent quality allows contracting parties to review patents to asses and challenge their validity). "Rent seeking behavior may arise when the holder of a poor quality patent seeks to enforce exclusionary rights that are probably invalid or seeks to stretch a valid narrow exclusionary right to cover

patent infringement litigation;[280] and "strengthen the incentives of private actors to engage in value-maximizing activities such as innovation or commercial transactions."[281]

The quality of an issued patent depends on the quality of the underlying Patent Office examination.[282] To a large extent the assurance of a good Patent Office examination is all about information.[283] It is doubtful that other patent reform efforts will significantly improve patent quality unless and until something is done about the information deficit at the Patent Office.[284] To explain, it should be clear that an examiner must have all of the relevant technical information in hand in order to accurately gauge patentability. But the Patent Office's limited resources,[285] combined with examiner production goals[286]

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acts outside the proper scope of the patent." Scott R. Boalick, *Patent Quality and the Dedication Rule*, 11 J. INTELL. PROP. L. 215, 240 (2004) (citing Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509, 512–16 (2003)); *see also* Wagner, *supra* note 3, at 2144 (explaining that the uncertainty brought about by a low-quality patent system allows it "[to] be exploited—whether by filing low-probability, high-cost suits or by seeking large numbers of low-quality patents to use as leverage for settlement").

280. Wagner, *supra* note 3, at 2144.

281. Wendy Schacht & John R. Thomas, *Patent Reform: Innovation Issues*, *in* PATENT TECHNOLOGY 1, 6 (Juanita M. Branes ed., 2007); *see also* Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries?*, 61 N.Y.U. ANN. SURV. AM. L. 317, 334–35 (2005) (explaining how patents of questionable quality can create ambiguities and uncertainties in the scope of ownership rights which can burden intellectual property transactions and thereby impede commercialization).

282. FTC REPORT, *supra* note 8, ch. 1, at 19 (citing ADVISORY COMM. ON INDUS. INNOVATION, INDUS. ADVISORY SUBCOMM. ON PATENT & INFO. POLICY, REPORT ON PATENT POLICY 153–55 (1979)).

283. *See id.* (arguing that the search for prior art is key to a quality patent and advocating for more resources to improve examination procedures); Cotropia, *Inequitable Conduct*, *supra* note 26, at 748 ("The assurance of a good patent quality is all about information . . . .").

284. *See supra* Part I.C.1. For a proposal which seeks to mitigate the Patent Office's information deficit, see Sean B. Seymore, *The Null Patent*, 53 WM. & MARY L. REV. 2041, 2041–42 (2012) (proposing a new medium of disclosure which would both provide examiners with more information and serve the public good by enriching the public storehouse of knowledge).

285. For example, an examiner's ability to get the relevant technical information is subject to the Patent Office's infrastructural limitations. *See* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77, 102 (2002) ("The predominance of U.S. patents [as cited prior art] may . . . reflect the limitations of the PTO systems for searching: the PTO is much more likely to find documents that it itself has generated."); Lemley, *Rational Ignorance*, *supra* note 11, at 1500 ("[M]uch of the most relevant prior art isn't easy to find—it consists of [third-party activities] that don't show up in any searchable database and will not be found by

and time pressures,[287] prevent this from happening. Indeed, for many inventions no one believes that the information that the examiner uncovers in the search of the prior art (for assessing novelty and nonobviousness) sufficiently represents the body of preexisting knowledge.[288] And notwithstanding the applicant's duty of candor,[289] it is hard to realistically believe that everything that the applicant knows about the invention ends up before the examiner.[290] When the examiner lacks the requisite technical information to gauge patentability, it is likely that low-quality patents will issue.[291]

The proposed regime helps ameliorate the information deficit. While it would not relieve the examiner of the burden of compiling sufficient evidence to establish a prima facie case of

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examiners in a hurry."); Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 196 (2007) ("A high-quality prior art search is difficult because of resource and time limitations."); Thomas, *Collusion*, *supra* note 2, at 318–19 (explaining that in newer technologies, examiners often cannot obtain the most recent technical literature); Bhaven N. Sampat, Determinants of Patent Quality: An Empirical Analysis 3 (Sept. 2005) (unpublished manuscript), *available at* http://www.immagic.com/eLibrary/ARCHIVES/GENERAL/COLUMBIA/C050902S.pdf (finding that examiners are less likely to find non-patent prior art and foreign patents).

286. "Production goals are the number of specific actions and decisions that patent examiners must make about patent applications they review during a two-week period." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-1102, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 2 (2007), *available at* http://www.gao.gov/new.items/d071102.pdf (last visited Nov. 29, 2012). Implicit in these goals is an estimate of the time it takes to review a patent application. *See id.* at 7.

287. The amount of time the Patent Office allots for an examiner to dispose of a case depends on factors like seniority and the technology involved. *See id.* Time estimates vary. *Compare* Thomas, *Collusion*, *supra* note 2, at 314 (estimating a sixteen- to seventeen-hour average time allotment), *with* Lemley, *Rational Ignorance*, *supra* note 11, at 1500 n.19 (aggregating time estimates, which range from eight to thirty-two hours, depending on the industry). As a part of internal patent reform, the Patent Office has reevaluated examination timelines. *See supra* note 27.

288. *See supra* note 285. This is particularly problematic in nascent, rapidly changing, or highly specialized fields where there is a paucity of relevant patent literature. BURK & LEMLEY, *supra* note 21, at 51 (explaining that while the Patent Office's accessible information sources might be sufficient to gauge patentability for mechanical and chemical fields, this may not be true in fields like software where the relevant information is inaccessible to the Patent Office).

289. *See supra* note 131 (discussing 37 C.F.R. § 1.56(a) (2012)).

290. *See supra* notes 129–31, 285 and accompanying text.

291. *See* sources cited *supra* notes 283–84 and accompanying text.

patentability,[292] placing the burden of persuasion on the applicant combined with the presumption of unpatentability would compel the applicant (rather than the examiner) to furnish information in close cases to carry the burden of proof and ultimately prevail.[293] If the applicant could not do so, a patent would not issue—which is not necessarily a bad outcome.[294] On the other hand, if a patent issues, it would be of higher quality vis-à-vis one issuing under the current regime because the application would have been subjected to a more robust examination.

But it is important to reiterate that the proposal would not place additional burdens on the examiner or the Patent Office. This is very important given the Patent Office's chronic funding concerns[295] and infrastructural limitations.[296] The proposal accepts the idea that "[i]mproving examination efficiency and patent quality should be a 'mutually shared responsibility' of both the PTO and patent applicants."[297] Thus, modifying the evidentiary rules of patent examination to be more evenly balanced

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292. *See supra* Part III.B.1.

293. *See supra* Part III.A.

294. *See infra* notes 303–06 and accompanying text.

295. The Patent Office's current resource problems might stem in part from a time in the recent past when some of the fee revenue it generated was diverted to the general treasury of the United States for use by other agencies. *See* Figueroa v. United States, 466 F.3d 1023, 1026–29 (Fed. Cir. 2006) (providing a historical account and reporting a Patent Office surplus of $545.1 million from fiscal years 1991 to 2004). At the end of fiscal year 2010, $814,759,000 in collected fees in the Patent Office's treasury account were "unavailable" to the agency. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2010, at 74 (2010) (discussing funding limitations). *But see* Mark A. Lemley, *Can the Patent Office Be Fixed?*, 15 MARQ. INTELL. PROP. L. REV. 295, 298–99 (2011) (arguing that fewer issued patents resulted in fewer maintenance fees and led to the Patent Office's problems in the late 2000s).

296. *See supra* note 285.

297. Brian E. Mack, Note, *PTO Rulemaking in the Twenty-First Century: Defining the Line Between Strategic Planning and Abuse of Authority*, 75 FORDHAM L. REV. 2105, 2151 (2007) (quoting Letter from Rick D. Nydegger, Chair, Patent Pub. Advisory Comm. of the U.S. Patent & Trademark Office, to Honorable Jon Dudas, Under Sec'y of Commerce for Intellectual Prop. 1 (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/ppac.pdf); *see also* Steve Lohr, *U.S. Seeking Stricter Rules on Qualifying for a Patent*, N.Y. TIMES, June 6, 2007, at C3 (quoting Jon Dudas, then Director of the United States Patent and Trademark Office, as stating: "There ought to be a shared responsibility for patent quality among the patent office, the applicants and the public . . . . If everything is done right at the front end, we'll have to worry a lot less about litigation later.").

between the examiner and the applicant comports with existing patent policy and is worthy of consideration.[298]

2. Filing Behavior

There is no doubt that the proposed regime would affect filing behavior. Faced with the presumption of unpatentability and the possible need to adduce proof, inventors with trivial or underdeveloped inventions contemplating a patent might realize that pursuing one would be a waste of time and money.[299] This would leave the inventor with two options. The first option would be not to file at all. Further product development might reveal, for example, that the invention would be technically infeasible or unlikely to gain much attention in the marketplace.[300] The inventor could conclude that the potential value of a conceived idea is not great enough to justify the expense of adducing sufficient proof for an inevitable fight over patentability.[301] For the patent system the upsides are many: one less application to be examined (and thus one less application to strain Patent Office resources and exacerbate the application overload problem),[302] the derailment of an assuredly low-quality patent,[303] one less obstacle for other inventors,[304] and one less patent document whose disclosure would add nothing to the public storehouse of technical knowledge.[305] So forgoing a patent in this context is not a bad result.[306]

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298. *See Patent Quality Improvement, Hearing Before the Subcomm. on Courts, the Internet, & Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. 24 (2003) (statement of John R. Thomas, Professor of Law, Georgetown University) (arguing that "the imposition of modest increases in the responsibilities of patent applicants," such as asking them to perform a prior art search, "strikes many observers as a sound policy choice," "comports with existing patent policies," and is "worthy of extended consideration").

299. JAFFE & LERNER, *supra* note 2, at 175.

300. Cotropia, *Early Filing*, *supra* note 175, at 88–93. Of course, an invention which is technically infeasible probably has little market worth. *Id.* at 123.

301. *Cf. id.* at 124 (using similar language in the context of an actual reduction to practice requirement). This scenario is one in which "some ideas will simply not make it." *Id.*

302. *Id.* at 104–05; *see also supra* note 17 and accompanying text.

303. Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341, 1369 (2009) ("Higher quality patents mean that fewer patents will be granted.").

304. *See* Cecil D. Quillen, Jr., *Innovation and the U.S. Patent System*, 1 VA. L. & BUS. REV. 207, 210 (2006) (discussing patent obstacles).

305. *Cf.* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that when the information disclosed in a patent becomes publicly available

The second option is to postpone filing until the invention is "further down the technology path."[307] Indeed, patent law contemplates that the inventor might spend *some* time perfecting the invention before filing.[308] From a policy perspective much good can come from the former; including better inventions,[309] more efficient patent examination,[310] improved patent quality,[311] reduced uncertainty,[312] and better disclosure.[313]

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it adds to the "general store of knowledge" and assumedly will stimulate ideas and promote technological development); *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that the full and complete disclosure of how to make and use the claimed invention "adds a measure of worthwhile knowledge to the public storehouse").

306. *See* sources cited *supra* note 2 (describing the kind of low quality patents that have resulted from the current system).

307. Cotropia, *Early Filing*, *supra* note 175, at 122.

308. Although the patent laws encourage prompt filing, "the public interest is also deemed to be served by allowing an inventor time to perfect his invention." TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 968 (Fed. Cir. 1984). So, while public use of the invention more than one year prior to filing can bar issuance of a patent under 35 U.S.C. § 102(b), a judicially created doctrine known as the experimental use exception can negate the bar by affording the inventor time to improve and perfect the invention. *See* City of Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 134–37 (1877) (articulating the experimental use doctrine); Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002) (listing objective criteria for determining if a use is experimental).

309. Further development and refinement of the invention "produce a better invention—whether it be safer, cheaper, more efficient, more durable, or more effective." Seymore, *Teaching Function*, *supra* note 172, at 654. When the refined embodiments are described and claimed, "the patentee can better protect the embodiment being marketed since it is that embodiment which competitors will likely target" and perhaps try to design around. *Id.* Further, forcing competitors to design around an invention lies at the heart of competition and ultimately benefits the consumer when competitors produce better and cheaper products. State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235–36 (Fed. Cir. 1985).

310. For example, if the invention is actually reduced to practice at the time of filing, it is much easier for the examiner to gauge compliance with the enablement requirement. *See* Seymore, *Teaching Function*, *supra* note 172, at 653 (arguing that working examples provide the best evidence "because . . . nothing is left to speculation or doubt."). Relatedly, the applicant's ability to provide more technical information about the invention allows for a more robust examination and mitigates the examiner's information deficit. *See* discussion *supra* Part I.C.1.

311. That delayed filing allows the applicant to generate more technical information about the invention and allows for a more robust examination which translates into improved patent quality. *See supra* notes 282–83 and accompanying text.

312. As Professor Christopher Cotropia explains:

> Additional technical information and definition reduce the uncertainty surrounding the invention before examination begins. The in-

Any discussion of delayed filing can be contentious given the oft-touted benefits of early filing in patent law.[314] Debates over the timing issue will certainly continue as the recent passage of the Leahy-Smith America Invents Act (AIA)[315] will convert the United States from a first-to-invent to a first-inventor-to-file patent system.[316] Under the proposed regime, an applicant might face a tradeoff between more pre-filing work and diligence (in part to adduce sufficient proof to prove patentabil-

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> ventor gains a better handle on whether the invention provides the wanted results. Furthermore, the additional time that passes while [development] is occurring produces more information of its own. This all places the actual examination forward in time, giving the inventor more certainty as to the invention's ultimate commercial worth.

Cotropia, *Early Filing*, *supra* note 175, at 123 (citing Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1075–76 (2007)).

313. "The resulting patent, by disclosing the post-conception refinements to the invention, will 'provide[] the public a readily available teaching of the most practicable device.'" Seymore, *Teaching Function*, *supra* note 172, at 654 (quoting Brief of Amicus Curiae American Intellectual Property Law Association in Support of Petitioner at 9, Pfaff v. Wells Elecs., Inc., 525 U.S. 55 (1998) (No. 97-1130)).

314. *See* Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558 (Fed. Cir. 1994) (rejecting an interpretation of § 112 which would "subvert the patent system's goal of promoting the useful arts through encouraging early disclosure"); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983) ("Early public disclosure is a linchpin of the patent system."). *Compare* John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 445 (2004) (arguing that early filing leads to reduced patent terms, thereby dedicating the invention to the public at an earlier time), *and* Kitch, *Nature and Function*, *supra* note 187, at 269–80 (arguing that early filing facilitates commercialization, coordinates the development of technology, and reduces wasteful duplicative efforts by competitors), *with* Seymore, *Teaching Function*, *supra* note 172, at 659–61 (arguing that ex ante incentives which encourage early filing can thwart innovation), *and* Cotropia, *Early Filing*, *supra* note 175, at 88–119 (discussing the costs of early filing).

315. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified as amended in scattered sections of 35 U.S.C.).

316. *See id.* § 3, 125 Stat. at 285–87 (amending 35 U.S.C. § 102(a) and repealing 35 U.S.C. § 102(g)). The difference matters when two or more parties independently develop the same or similar invention around the same time. Under the first-to-invent system, "the patent will be awarded to the applicant who was the first inventor in fact . . . even if the first inventor was not the first person to file a patent application directed towards that invention." Schacht & Thomas, *supra* note 281, at 10. Under the first-inventor-to-file system, "the inventor who first filed an application at the patent office is presumptively entitled to the patent," thereby making the question of "[w]hether or not the first applicant was actually the first individual to complete the invention in the field . . . irrelevant." *Id.* at 10–11.

ity) and the perceived need to race to the Patent Office with the underdeveloped invention (and hope for the best).[317]

While it is certainly true that the AIA redefines prior art,[318] it is far from clear how the first-inventor-to-file system will affect filing behavior. To illustrate, consider the general rule under the AIA that any disclosure by a third party before the inventor's filing date will ordinarily defeat patentability.[319] However, a third-party disclosure will not qualify as prior art if within one year of filing either the inventor had already disclosed the invention before the third party[320] or the third party somehow derived its disclosure from the inventor.[321] Surveying this new landscape, Professors Dennis Crouch and Jason Rantanen suggest that inventors will have two low-cost options to secure an early filing date.[322] One is to file a provisional patent application—an option available under existing law.[323] The

317. To the extent that the first-inventor-to-file regime forces inventors to race to the Patent Office, this "would encourage premature and sketchy technological disclosures in hastily-filed patent applications." Schacht & Thomas, *supra* note 281, at 11 (citing Coe A. Bloomberg, *In Defense of the First-to-Invent Rule*, 21 AIPLA Q.J. 255, 260 (1993)).

318. *See* Leahy-Smith America Invents Act § 3, 125 Stat. at 285–86 (amending 35 U.S.C. § 102); Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 22–87 (2012) (discussing the AIA's prior art provisions). The changes will apply to patent applications with an effective filing date after March 16, 2013. *See id.* § 3, 125 Stat. at 288.

319. *Id.* § 3, 125 Stat. at 285–87 (to be codified as 35 U.S.C. § 102(a)). By contrast, under the current regime, a one-year grace period applies to disclosures made by the inventor or third parties before filing. *See* 35 U.S.C. § 102(b) (2006).

320. America Invents Act § 3, 125 Stat. at 286 (to be codified as 35 U.S.C. § 102(b)(1)(B)).

321. *Id.* (to be codified as 35 U.S.C. § 102(b)(1)(A)).

322. *See* Dennis Crouch, *Disclosure under the AIA: Introducing The Poor Man's Provisional Patent Application*, PATENTLY-O (Sep. 21, 2011, 6:16 PM), http://www.patentlyo.com/patent/2011/09/disclosure-under-the-aia-the-poor-mans-provisional-patent-application.html [hereinafter Crouch, *Disclosure Under the AIA*]; Jason Rantanen, *The Effects of the America Invents Act on Technological Disclosure*, PATENTLY-O (Sept. 8, 2011, 3:01 PM), http://www.patentlyo.com/patent/2011/09/the-effects-of-the-america-invents-act-on-technological-disclosure.html.

323. A provisional patent application (PPA) allows an inventor to obtain an early filing date for the invention before the inventor is ready to draft a claim or a full application. *See* 35 U.S.C. § 111 (2006). A PPA is not examined and only requires a minimal filing fee. *Id.* The inventor must, however, submit a regular, "nonprovisional" application within one year, or the PPA is automatically abandoned. 35 U.S.C. § 119(e)(1). In short, the PPA provides an inventor with an easy and inexpensive mode of entry into the U.S. patent system.

other is to simply make an early, pre-filing disclosure.[324] The ultimate choice of whether or when to file or disclose will depend on the inventor's overall patenting strategy.[325]

CONCLUSION

It is far too easy to get a (bad) patent. Despite administrative, legislative, and judicial efforts at patent reform, it is still the case that anyone who files a patent application on anything will eventually get a patent. This is because the presumption of patentability and allocations of burdens of proof put applicants in a favorable position from the very outset of patent examination. As this Article has shown, many of the pressing problems in the patent system can be traced to this paradigm. The situation is much different under the proposed regime which rebalances the scales of patentability. By placing a heavier burden upon the applicant, getting a patent would be far from guaranteed. This would cure many ills of the patent system and promote broader goals of patent policy.

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324. Professor Crouch has explained the benefits of this option:

> Self-disclosure offers similar benefits to that of a provisional application in that it is cheap with few formalities and provides an additional year of delay. In fact, public disclosure should be cheaper and easier than filing a provisional application. In the same way that a provisional application is seen as a poor man's patent application, I suggest that public disclosure will be seen as a poor man's provisional application or a "really poor man's patent application." The disclosure allows an applicant to buy an additional year of delay with few capital expenditures and without losing patent term but instead merely shifting the term forward in time.

Crouch, *Disclosure Under the AIA*, *supra* note 322.

325. An important constraint on a PPA is that it must include a written description which satisfies the requirements of § 112. New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294 (Fed. Cir. 2002). Pre-filing disclosure might cause problems for inventors who contemplate filing abroad. The one-year grace period available in the United States is not available in many foreign countries. *See, e.g.*, Convention on the Grant of European Patents art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 272. Most of them have an absolute novelty requirement such that any pre-filing disclosure, including activity by the inventor, is patent-defeating. *Id.* Accordingly, if foreign filing is a possibility, the applicant must take steps to avoid inadvertent or premature disclosure.